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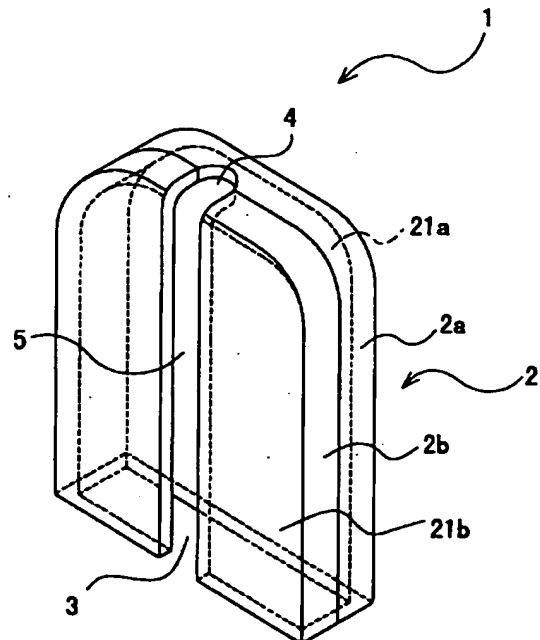
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(54) 【発明の名称】 白血球除去器用硬質ホルダー

(57) 【要約】

【課題】 軟質樹脂製のハウジングを有する白血球除去器に装着して白血球除去器の適切な濾過を可能とする硬質ホルダーの提供に関する。

【解決手段】 硬質ホルダー1は、軟質樹脂製袋状ハウジング42と、白血球除去用フィルター部材45と、血液流入ポート46および血液流出ポート47とを備える白血球除去器40に装着するものである。そして、硬質ホルダー1は、白血球除去器40を収納するための本体部2を備え、本体部2は、使用時に白血球除去器と接触するほぼ平行に形成された向かい合う平板状部分2a、2bを備え、本体部2の向かい合う平板状部21a、21bの間隔は、白血球除去器40の厚み以上となっている。



濾過速度が遅くなるおそれがあった。さらに、特開平11-206875号公報には、軟質樹脂により作製されたハウジングを有する白血球除去器と、それを収納するための硬質収納容器を備える白血球回収セットが記載されている。これらは、内部に血液を通液した白血球除去器の容量、具体的には、流入側血液室の容量を規制することにより、適度に白血球を回収するものとなっている。

【0004】しかしながら、特開平11-206875号公報に記載の白血球回収セットは、白血球除去器を圧縮した状態で硬質容器に収納するため、軟質樹脂製ハウジングと白血球除去フィルターとが密着し、白血球除去器内に血液を通液したとしても、白血球除去器内の血液の流通を妨げることとなり濾過速度の低下を引き起こすこととなる。特に、フィルター部材が多孔質体の場合、除去器を圧縮した状態で硬質容器内に収納すると、多孔質体の孔がつぶれ、血液がフィルターに流入しなくなるおそれがあった。

【0005】

【発明が解決しようとする課題】従来の硬質ホルダーは、白血球除去器と一体に作製されることが多いため、白血球除去器に硬質ホルダーを装着した状態では、白血球除去器のみの場合より製品の嵩が高くなり、輸送費の増加につながっていた。さらに、白血球除去器毎に、予め射出成形等により作製した硬質ホルダーを、熱融着、接着あるいはネジ止め等により固定し装着していたため、装着工程が煩雑となり、製造コストの増加につながっていた。また、従来の硬質ホルダーにおいては、白血球除去器に装着した後は取り外すことが困難であるため、濾過使用後は両方まとめて廃棄することとなり廃棄物量増加等の問題を生じていた。そこで、本発明の目的は、軟質樹脂製のハウジングを有する白血球除去器に装着して白血球除去器の適切な濾過を可能とする硬質ホルダー、および、使用前に軟質樹脂製のハウジングを有する白血球除去器に容易に装着でき、使用後は白血球除去器から容易に取り外すことのできる硬質ホルダーを提供することにある。

【0006】

【課題を解決するための手段】上記目的を達成するものは、軟質樹脂製袋状ハウジングと、該ハウジング内を流入側血液室と流出側血液室とに区分するように設けられた白血球除去用フィルター部材と、前記流入側血液室と連通する血液流入ポートと、前記流出側血液室と連通する血液流出ポートとを備えている白血球除去器を収納するための白血球除去器用硬質ホルダーである。そして、該硬質ホルダーは、前記白血球除去器を収納するための本体部を備え、該本体部は、使用時に白血球除去器と接触するほぼ平行に形成された向かい合う平板状部分を備え、該本体部の向かい合う平板状部分の間隔は、前記白血球除去器の厚み以上となっている。

【0007】そして、前記白血球除去器用硬質ホルダーは、一端に設けられた白血球除去器挿入用開口部と、他端側に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な貫通部と、該貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続されたチューブの誘導用の誘導用切り欠き部を備えていることが好ましい。また、前記白血球除去器用硬質ホルダーは、前記向かい合う平板状部分の側端に位置する白血球除去器挿入用開口部と、上端に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な上端側貫通部と、下端に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な下端側貫通部と、前記上端側貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続されたチューブの誘導用の上端側誘導用切り欠き部と、前記下端側貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続されたチューブの誘導用の下端側誘導用切り欠き部とを備えていることが好ましい。

【0008】さらに、前記白血球除去器用硬質ホルダーは、前記向かい合う平板状部分の側端に位置する白血球除去器挿入用開口部と、上側の平板状部分の中央部付近に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な上側貫通部と、下側の平板状部分の中央部付近に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な下側貫通部と、前記上側貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続されたチューブの誘導用の上側誘導用切り欠き部と、前記下側貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続された前記チューブの誘導用の下側誘導用切り欠き部とを備えていることが好ましい。また、前記本体部は、第1の平板部と、該第1の平板部に開閉可能に軸支されるとともに、前記白血球除去器を収納する閉塞状態にて前記第1の平板部とほぼ平行となる第2の平板部とを備え、さらに、前記本体部は、前記白血球除去器収納状態にて、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な上端側貫通部および前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な下端側貫通部を備えていることが好ましい。また、前記本体部は、第1の平板部と、該第1の平板部に着脱可能であるとともに、前記白血球除去器を収納する装着状態にて前記第1の平板部とほぼ平行となる第2の平板部とを備え、さらに、前記本体部は、前記白血球除去器収納状態にて、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な上端側貫通部および前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な下端側貫通部を備えていることが好ましい。

球除去用フィルター部材45は、熱可塑性軟質樹脂製シート状フレーム451とフレーム451に周縁部が直接もしくは間接的に固着された濾過機能部材452とからなる。濾過機能部材452は、複数の濾材の積層物により形成されている。ここで用いている白血球除去用フィルター部材45は、濾過機能部材452が形成する濾過機能部位と濾過機能部位の周縁全周に形成された非濾過機能部位を備えている。そして、白血球除去用フィルター部材45は、2枚の熱可塑性軟質樹脂シート間に挟まれた状態となっており、さらに、熱可塑性軟質樹脂製シート状フレーム451の周縁部が2枚の熱可塑性軟質樹脂シートに熱融着されている。これにより、白血球除去用フィルター部材45は、2枚の熱可塑性軟質樹脂シート421、422内の空間（ハウジング42内）を流入側血液室43と流出側血液室44とに区分している。そして、血液流入ポート46を構成する軟質樹脂チューブが、流入側血液室43と連通するように、言い換えれば、軟質樹脂チューブの一端開口が流入側血液室43内において開口するように、2枚の熱可塑性軟質樹脂シート間の一端側（上端側）の中央部に熱融着されている。同様に、血液流出ポート47を構成する軟質樹脂チューブが、流出側血液室44と連通するように、言い換えれば、軟質樹脂チューブの一端開口が流出側血液室44内において開口するように、2枚の熱可塑性軟質樹脂シート間の他端側（下端側）の中央部に熱融着されている。【0016】特に、この白血球除去器40では、白血球除去用フィルター部材45は、図11に示すように、熱可塑性軟質樹脂製シート状フレーム451は一端側（上端側）の中央部および他端側（下端側）の中央部に外方に突出する短い帯状の延出部451a、451bを備えており、血液流入ポート46を構成する軟質樹脂チューブは、延出部451aと流入側樹脂シート421間に位置するようにシート421、422に融着され、血液流出ポート47を構成する軟質樹脂チューブは、延出部451bと流出側樹脂シート422間に位置するようにシート421、422に融着され、これにより、血液流入ポート46は、流入側血液室43とのみ連通し、血液流出ポート47は流出側血液室44とのみ連通している。そして、血液流入ポート46および血液流出ポート47には、それぞれ白血球除去器に被濾過物質（図示せず）を導入するためのチューブ416、濾液（図示せず）を排出するためのチューブ417が接続されている。これにより、チューブ416は、血液流入ポート46を介し流入側血液室43と連通し、チューブ417は、血液流出ポート47を介し、流出側血液室44と連通している。チューブ416、417と血液流入ポート46、血液流出ポート47の接続は、ポート416、417を構成する軟質チューブの内側にチューブ416、417を挿入し融着することにより行われる。このため、チューブの外径は、ポートの内径とほぼ同じ大きさに作製され

ていることが好ましい。チューブの形成材料としては、血液流入ポート46および血液流出ポート47に使用される樹脂が好ましく、このうち、血液流入ポート46および血液流出ポート47と融着容易な樹脂が好ましい。【0017】また、白血球除去用フィルター部材45は、図11に示す破線より外側において、ハウジング42（2枚の熱可塑性軟質樹脂シート421、422間）に融着されている。このため、白血球除去器40は、流出側血液室44の周縁部に濾過機能部位452と接触しない部位（言い換えれば、濾過機能を持たない部位、非濾過機能部位）とハウジング内面間により形成された血液流路426を備えている。同様に、白血球除去器40は、流入側血液室43の周縁部に濾過機能部位452と接触しない部位、言い換えれば、濾過機能を持たない部位、非濾過機能部位とハウジング内面間により形成された血液流路427を備えている。このような非濾過機能部位とハウジング42の内面間により形成された血液流路をハウジング内の周縁部に有することにより、ハウジング42内部の周縁部での血液の流通を良好とし周縁部における残血を防止する。さらに、このような血液流路が流出側血液室44内の血液流出ポート47付近に存在することにより、リブ423間の流路425を流れた濾過血液が血液流出ポート47に良好に誘導されるためより、濾過速度の低下がより少ないものとなっている。そして、白血球除去器は、5ml以上のエアを保留していることが好ましい。ハウジング42を構成する熱可塑性軟質樹脂シート421、422、白血球除去用フィルター部材45の熱可塑性軟質樹脂製シート状フレーム451、血液流入ポート46および血液流出ポート47の形成材料としては、可撓性の熱可塑性樹脂が使用される。

【0018】ハウジング42を構成する熱可塑性軟質樹脂シート421、422、白血球除去用フィルター部材45の熱可塑性軟質樹脂製シート状フレーム451、血液流入ポート46および血液流出ポート47の固着は、接着剤を用いない融着が好ましい。溶着は、ヒートシールによる外部加熱溶着、高周波ウェルダ、超音波ウェルダによる内部溶着でもよい。また溶着の方法は、上記の部材をすべて同時に融着させても、ステップを分けて行ってもよい。

【0019】そして、白血球除去用フィルター部材45の濾過機能部位452は、多孔質体もしくは不織布からなる複数の濾材の積層物となっている。具体的には、6枚の濾材452a、452b、452c、452d、452e、452fが積層されている。なお、濾材の積層枚数としては、2～10枚が好適である。そして、この実施例では、濾材の積層枚数が多いため、何枚かの濾材（例えば、3～5枚）は、融着補助用シート状フレーム453に融着され、濾材が融着された融着補助用シート状フレーム453の外側周縁部が熱可塑性軟質樹脂製シ

は、図6のA-A線断面(図8)の断面積以上に作製されているため、白血球除去器40を、その上端から硬質ホルダー1内に挿入することができる。なお、開口部3付近を下端に向かって拡張するテーパ状に作製することにより、白血球除去器を容易に挿入できるようにしてもよい。

【0025】貫通部4は、白血球除去器40の血液流入ポート46もしくは血液流入ポート46に接続されるチューブ416が貫通可能な部分である。具体的には、貫通部4は、白血球除去器40に硬質ホルダー1を装着する際には、血液流入ポート46に接続されたチューブ416が通過する部分となっており、装着後は、血液流入ポート46が通過する部分となっている。このため、硬質ホルダーを装着した状態においても、白血球除去器内に被濾過物質を導入することができる。また、実施例では、貫通部4は、本体部2の上端の血液流入ポート46に対応する位置に形成されているが、血液流入ポート46および血液流入ポート46に接続されたチューブ416内の液体の流通を妨げなければ、血液流入ポート46側(図1の上端)のいかなる位置に作製されていてもよい。また、貫通部4は、本発明の実施例では、ポート46の外径と同じ円形に作製されているが、これに限られず、楕円形状等に作製してもよい。また、貫通部4の内径は、ポート46の外径に対して、-1mm以上、+10mm以内の大きさに作製することが好ましい。これは、ポート46の外径より1mm程度狭くても、ポート46の柔軟性、伸縮性のために貫通部4を通過させることが可能であり、また10mm程度大きくてもポート46が貫通部4から外れることがないからである。なお、実施例では、白血球除去器40に硬質ホルダーを装着した状態では、ポート46が貫通部4を貫通しているが、これに限られず、チューブ416が貫通するように作製してもよい。この場合の貫通部の内径も、チューブの外径に対して、-1mm以上、+10mm以内の大きさに作製されているものであることが好ましい。なお、本発明の実施例では、本体部2の上端に貫通部4を、下端に開口部3を形成しているが、これに限られるものではなく、上端に挿入用開口部を、下端に貫通部を形成してもよい。

【0026】誘導用切り欠き部5は、貫通部4から開口部3まで延びており、白血球除去器40に硬質ホルダーを装着する際、チューブ416を貫通部4に誘導するための部分となっている。また、切り欠き部5は、本体部2の白血球除去器40の流出側血液室44側において、貫通部4から開口部3まで一直線に形成されている。このように、流出側血液室側44に切り欠き部5を形成したのは、流入側血液室側43に切り欠き部を形成すると、流入側血液室43(ハウジング421)が拡張した際、本体部の内壁が広がり、あるいは、切り欠きからハウジング421がはみ出ることであり確実に容量規制を

行うことができないからである。なお、切り欠き部は、上述したように一直線に作製されているものに限らず、チューブ416が切り欠き部から外れにくいように、貫通部4から挿入用開口部3の途中で曲折等するように作製してもよい。なお、切り欠き部5の幅は、貫通部4と同じ理由によりポート46もしくはチューブ416の外径に対して、-1mm以上、+10mm以内の大きさに作製することが好ましい。なお、貫通部の内径は、ポートの外径より広く、切り欠き部の幅は、チューブの外径より狭く作製されていることがより好ましい。このように作製することにより、チューブが硬質ホルダーから外れにくくなるとともにポートおよびポートに接続されたチューブを通過する液体の流れを妨げることがない。

【0027】また、硬質ホルダー1の肉厚は、ほとんどの部分が2mm以上であることが好ましい。これは、硬質樹脂により作製された容器であっても肉厚が薄いと白血球除去器の拡張により硬質ホルダーが押し広げられ、適当に容量規制を行うことができないからである。また、ほとんどとあるのは、硬質ホルダー1の一部が2mm未満でも上記目的を達成することができるからである。例えば、図1に示す硬質ホルダー1の上端部の肉厚が2mm未満であっても、適切に白血球除去器の容量規制を行うことができる。硬質ホルダーの形成材料としては、ポリプロピレン、硬質塩化ビニル、ポリスチレン、ポリエチレン等が使用されるが、より好ましくは、ポリプロピレンである。なお、硬質ホルダーの肉厚は、2mm以上の範囲のうち、2~3mmがより好ましい。

【0028】また、硬質ホルダー1は、その内面に複数の突起状物(図示せず)を備えていることが好ましい。また、硬質ホルダー1は、その内面に複数のリブ(図示せず)を備えていることが好ましい。これらは、白血球除去器と硬質ホルダーとの癒着を防止し、白血球除去器の使用後、容易に硬質ホルダーを取り外すことができるように設けられている。なお、上述した突起状物およびリブは、白血球除去器内を通過する液体の流れる方向に沿って配置されていることが好ましい。これにより、白血球除去器内を通過する液体の流れを妨げることがない。突起状物の形状は、円錐状、多角錐状、半球状などが好適であり、特に、半球状が好ましい。突起の高さ(高低差)は、0.2~2mmが好適であり、特に、0.5~1mmが好適である。また、突起の底面の大きさは、0.5~10mm²程度が好適である。また、突起の数は、突起の底面積によっても相違するが、1cm²当たり3~50個程度、突起間の距離1~10mmが好適である。リブの形状は、三角錐状、半球状などのように先端に向かって幅が狭くなるものが好適である。リブの間隔は、2~6mm程度が好適であり、リブはほぼ等間隔となっている。また、リブの幅は、1~3mm程度が好適であり、リブの高さは、1~3mm程度が好適である。

い。硬質ホルダー10の本体部12の内部の大きさは、向かい合う平板状部分121a、121bの間隔が白血球除去器の厚みに対して、0~3mm増し、図2の長手方向の長さが白血球除去器の長さに対して、0~3mm増し、図2の長手方向と直交する方向の長さが白血球除去器の幅に対して、0~3mm増しであることが好ましい。

【0035】挿入用開口部13は、白血球除去器40を本体部12に挿入する部分であり、向かい合う平板状部分121a、121bの側端に形成されている。また、開口部13は、図6の白血球除去器40のB-B線断面(図9)の断面積以上の大きさに作製されているため、白血球除去器40をその側面側から硬質ホルダー10に挿入することができる。なお、硬質ホルダー1と同様に挿入用開口部13の開口部付近を開口端に向かってテーパ状に拡張するように作製してもよい。

【0036】上端側貫通部14は、本体部12の上端に設けられ、白血球除去器40の血液流入ポート46が貫通する部分であり、下端側貫通部15は、本体部12の下端に設けられ、白血球除去器40の血液流出ポート47が貫通する部分である。このため、白血球除去器40に硬質ホルダー10を装着した状態においても白血球除去器40は、濾過を行うことができる。また、実施例では、本体部12の血液流入ポート46に対応する位置に上端側貫通部14が、本体部12の血液流出ポート47に対応する位置に下端側貫通部15が形成されているが、血液流入ポート46および血液流出ポート47並びに血液流入ポート46および血液流出ポート47に接続されたチューブ416、417を通過する液体の流れを妨げなければ、それぞれ、本体部12の上端側(血液流入ポート46側)および血本体部12の下端側(血液流出ポート47側)のいかなる位置に作製されていてもよい。また、上端側貫通部14、下端側貫通部15は、実施例では、ポート46およびポート47の外径と同じ円形に作製されているが、楕円形状等に作製してもよい。なお、貫通部14、15の内径の大きさは、硬質ホルダー1と同様にポートの外径に対して、-1mm以上、+10mm以内であることが好ましい。また、実施例では、白血球除去器40に硬質ホルダーを装着した状態では、ポート46が上端側貫通部14を貫通し、ポート47が下端側貫通部17を貫通するものとなっているが、これに限らず、チューブ416が上端側貫通部14を貫通し、チューブ417が下端側貫通部15を貫通するものであってもよい。この場合の貫通部の内径は、チューブの外径に対して、-1mm以上、+10mm以内の大きさに作製されているものであることが好ましい。

【0037】上端側誘導用切り欠き部16は、実施例では、血液流入ポート46もしくはチューブ416を開口部13から上端側貫通部14まで誘導する部分であり、

くはチューブ417を、開口部13から下端側貫通部15まで誘導する部分となっている。なお、実施例では、切り欠き部16、17は、それぞれ上端側貫通部14、下端側貫通部15から挿入用開口部13まで、一直線に作製されているが、これに限らず、途中で曲折等させることにより、チューブが硬質ホルダーから外れにくくしたものであってもよい。切り欠き部16、17の幅は、上端側貫通部14、下端側貫通部15の場合と同様にポートもしくはチューブの外径に対して、-1mm以上、+10mm以内に作製されていることが好ましい。

【0038】なお、貫通部の内径は、ポートの外径より広く、切り欠きの幅が、チューブの外径より狭く作製されていることがより好ましい。このように作製することにより、ポートが硬質ホルダーから外れにくくなるとともにポートおよびポートに接続されたチューブを通過する液体の流れを妨げることがない。また、硬質ホルダー10の肉厚は、硬質ホルダー1の場合と同様にほとんどの部分が2mm以上であることが好ましい。硬質ホルダーの形成材料としては、硬質ホルダー1と同様のものが使用される。なお、硬質ホルダー10の肉厚は、2mm以上の範囲のうち、2~3mmがより好ましい。また、硬質ホルダー10は、硬質ホルダー1と同様にその内面に複数の突起状物(図示せず)を備えていることが好ましい。さらに、硬質ホルダー10は、硬質ホルダー1と同様に複数のリブ(図示せず)を備えていることが好ましい。なお、突起状物またはリブの形状および大きさは、硬質ホルダー1と同様であることが好ましい。また、硬質ホルダー10は、硬質ホルダー1と同様に透明性が高い樹脂により作製されていることが好ましい。透明性が高い樹脂としては、硬質ホルダー1と同様のものが好ましい。なお、白血球除去器内の状態を確認することができれば、完全に透明である必要はなく、半透明な樹脂により作製されていてもよい。

【0039】次に、本発明の実施例の硬質ホルダー10の製造方法について説明する。まず、平板状部分121aを含む表側部材12aと平板状部分121bを含む裏側部材12bを別々に射出成形する。次に、表側部材12aの白血球除去器40を収納する側と裏側部材12bの白血球除去器40を収納する側を内側に向けて両者が対向するように配置し、互いの周縁を接合することにより、硬質ホルダー10が作製される。接合は、硬質ホルダー1と同様の方法にて行われる。

【0040】次に、本発明の他の実施例である硬質ホルダー10の使用法について説明する。まず、白血球除去器40の側面側を硬質ホルダー10の側面に形成された挿入用開口部13から挿入し、白血球除去器40全体を硬質ホルダー10内に収納する。この場合、血液流入ポート46は、挿入用開口部13から切り欠き部16を通過し上端側貫通部14に誘導され、同様に、血液流出ポート47は、挿入用開口部13から切り欠き部17を

増し、図3の長手方向の長さが白血球除去器の直径に対して、0~3mm増し、図3の長手方向と直交する方向の長さが白血球除去器の直径に対して、0~3mm増しであることが好ましい。

【0045】白血球除去器挿入用開口部23は、白血球除去器70を本体部22に挿入する部分であり、向かい合う平板状部分221a、221bの側端に形成されている。また、開口部23は、図15の白血球除去器70の中央断面図(図16)の断面積以上の大きさに作製されている。従って、白血球除去器70をその側面側から硬質ホルダー20に挿入することができる。なお、硬質ホルダー1と同様に挿入用開口部23の開口部付近を開口端に向かってテーパ状に拡張するように作製してもよい。

【0046】上側貫通部24は、実施例では、本体部22の上側の平板状部分221aの中央部の血液流入ポート76に対応する位置に設けられ、白血球除去器70を硬質ホルダー20に挿入した状態では、血液流入ポート76が貫通可能な部分となっている。一方、下側貫通部25は、本体部22の下側の平板状部分221bの中央部の血液流出ポートに対応する位置に設けられ、白血球除去器70を硬質ホルダーに収納した状態では、血液流出ポート77が貫通可能な部分となっている。なお、上側貫通部24、下側貫通部25が形成される位置は、上述したものに限られず、血液流入ポート76および血液流出ポート77並びに血液流入ポート76および血液流出ポート77に接続されたチューブ716、717を通過する液体の流れを妨げなければ、それぞれ、本体部22の上側の平板状部分221a(血液流入ポート76側)および血本体部22の下側の平板状部分221b(血液流出ポート77側)のいかなる位置に作製されていてもよい。また、上側貫通部24、下側貫通部25は、実施例では、ポート76およびポート77の外径と同じ円形に作製されているが、楕円形状等に作製されていてもよい。また、上側貫通部24、下側貫通部25内径の大きさは、硬質ホルダー10と同様にポートの外径に対して、-1mm以上、+10mm以内であることが好ましい。なお、実施例では、白血球除去器70に硬質ホルダーを装着した状態では、ポート76が上側貫通部24を貫通し、ポート77が下側貫通部25を貫通するものとなっているが、これに限られず、チューブ716が上側貫通部24を貫通し、チューブ717が下側貫通部25を貫通するものであってもよい。この場合の貫通部の内径は、チューブの外径に対して、-1mm以上、+10mm以内の大きさに作製されているものであることが好ましい。

【0047】また、硬質ホルダー20は、上側貫通部24から開口部23まで延びる血液流入ポート76の誘導用の上側誘導用切り欠き部26と、下側貫通部25から開口部23まで延びる血液流出ポート77の誘導用の下

側誘導用切り欠き部27とを備えている。また、実施例では、切り欠き部26、27は、それぞれ上側貫通部24、下側貫通部25から挿入用開口部23まで、一直線に作製されているが、これに限られず、途中で曲折等させることにより、チューブが硬質ホルダーから外れにくくしたものであってもよい。また、切り欠き部26、27の幅は、上側貫通部24、下側貫通部25の場合と同様にポートもしくはチューブの外径に対して、-1mm以上、+10mm以内に作製されていることが好ましい。

10. い。

【0048】なお、貫通部の内径は、ポートの外径より広く、切り欠き部の幅が、チューブの外径より狭く作製されていることが好ましい。このように作製することにより、ポートが硬質ホルダーから外れにくくするとともにポートおよびポートに接続されたチューブを通過する液体の流れを妨げないものとなる。また、硬質ホルダー20の肉厚は、硬質ホルダー1の場合と同様にほとんどの部分が2mm以上であることが好ましい。硬質ホルダーの形成材料としては、硬質ホルダー1と同様のものが使用される。なお、硬質ホルダー20の肉厚は、2mm以上の範囲のうち、2~3mmがより好ましい。

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【0049】また、硬質ホルダー20は、硬質ホルダー1と同様にその内面に複数の突起状物(図示せず)。また、硬質ホルダー20は、硬質ホルダー1と同様に複数のリブ(図示せず)を備えていることが好ましい。なお、突起状物またはリブの形状および大きさは、硬質ホルダー1と同様であることが好ましい。また、硬質ホルダー20は、硬質ホルダー1と同様に透明性が高い樹脂により作製されていることが好ましい。透明性の高い樹脂としては、硬質ホルダー1と同様のものが好ましい。なお、白血球除去器内の状態を確認することができれば、完全に透明である必要はなく、半透明な樹脂により作製されていてもよい。

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【0050】次に、本発明の実施例の硬質ホルダー20の製造方法を説明する。まず、硬質ホルダー20は、上側の平板状部分221aを含む表側部材22aと下側の平板状部分221bを含む裏側部材22bとを別々に射出成形する。次に、表側部材22aの白血球除去器を収納する側と裏側部材22bの白血球除去器を収納する側とを内側に向けて両者が対向するように配置し、互いの周縁を接合することにより作製される。接合は、上述した方法により行われる。

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【0051】次に、本発明の他の実施例である硬質ホルダー20の使用方法について説明する。まず、白血球除去器70を、その側面側から硬質ホルダー20の側面に形成された挿入用開口部23から挿入し、白血球除去器70全体を収納する。この際、血液流入ポート76は、挿入用開口部23から切り欠き部26を通過し上側貫通部24に誘導される。同様に、血液流出ポート77は、挿入用開口部23から切り欠き部27を通過し、下側貫

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ことが好ましい。なお、実施例では、白血球除去器40に硬質ホルダーを装着した状態では、ポート46が上端側貫通部35を貫通し、ポート47が下端側貫通部36を貫通するものとなっているが、これに限られず、チューブ416が上端側貫通部35を貫通し、チューブ417が下端側貫通部36を貫通するものであってもよい。この場合の貫通部の内径は、チューブの外径に対して、-1mm以上、+10mm以内の大きさに作製されているものであることが好ましい。

【0057】また、本体部32は、第1の平板部32a 10の軸支する部分と反対側の側端に設けられた固定用凹部34aと、第2の平板部32bの軸支する部分と反対側の側端に設けられた固定用凸部34bとが嵌合することにより閉塞状態で固定される。このような構成により、使用後は、第1の平板部から第2の平板部を容易に取り外すことができる。なお、本体部32の第1の平板部と第2の平板との着脱方法は、上述したものに限られない。

【0058】また、硬質ホルダー30の肉厚は、硬質ホルダー1の場合と同様にほとんどの部分が2mm以上であることが好ましい。硬質ホルダーの形成材料として 20は、硬質ホルダー1と同様のものが使用される。なお、硬質ホルダー30の肉厚は、2mm以上の範囲のうち、2~3mmがより好ましい。また、硬質ホルダー30は、硬質ホルダー1と同様にその内面に複数の突起状物（図示せず）。また、硬質ホルダー30は、硬質ホルダー1と同様に複数のリブ（図示せず）を備えていることが好ましい。なお、突起状物またはリブの形状および大きさは、硬質ホルダー1と同様であることが好ましい。また、硬質ホルダー30は、硬質ホルダー1と同様に透 30明性が高い樹脂により作製されていることが好ましい。透明性の高い樹脂としては、上述したものが好ましい。なお、白血球除去器内の状態を確認することができれば、完全に透明である必要はなく、半透明な樹脂により作製されていてもよい。

【0059】次に、硬質ホルダー30の製造方法について説明する。まず、硬質ホルダー30の平板状部分321aを含む第1の平板部32aと平板状部分321bを含む第2の平板部32bとを別々に射出成形する。次に、第1の平板部32aの白血球除去器40を収納する側と第2の平板部32bの白血球除去器40を収納する側を内側に向けて両者が対向するように配置し、第1の平板部32aに形成された凹部33aと第2の平板部32bに形成された凸部33bとを嵌合させ、硬質ホルダー30を作製する。 40

【0060】次に、本発明の他の実施例の硬質ホルダー30の使用方法について図4を用いて説明する。まず、本体部32を開いて、第1の平板部32a、第2の平板部32bのいずれか一方に白血球除去器40を配置する。このとき、血液流入ポート46は、上端側貫通部3 50

5を構成する部分に配置され、血液流出ポート47は、下端側貫通部36を構成する部分に配置されている。次に、第1の平板部32aと第2の平板部32bとを閉じ合わせ、固定用凹部34aと固定用凸部34bとを嵌合させ、白血球除去器40に硬質ホルダー30を装着する。硬質ホルダー30を白血球除去器40から取り外す場合は、装着方法の手順と逆の手順を行えばよい。以上より、硬質ホルダー30は、濾過前においては、白血球除去器40に容易に装着できるとともに、濾過後は白血球除去器40から容易に取り外すことができるものとなっている。

【0061】次に、本発明の他の実施例である白血球除去器用硬質ホルダーについて説明する。図5は、本発明の他の実施例である白血球除去器用硬質ホルダーの斜視図である。この実施例の白血球除去器用硬質ホルダー80は、白血球除去器40の袋状ハウジング42部分を収納するための本体部82を備え、本体部82は、使用時に白血球除去器40の軟質樹脂製袋状ハウジング42の両面と接触するほぼ平行に形成された向かい合う平板状部分821a、821bを備え、本体部82の向かい合う平板状部分821a、821bの間隔は、白血球除去器40の厚み以上となっている。また、本体部82は、第1の平板部82aと、第1の平板部82aに着脱可能であるとともに、白血球除去器40を収納する装着状態にて第1の平板部82aとほぼ平行となる第2の平板部82bとを備え、さらに、本体部82は、白血球除去器40収納状態にて、白血球除去器40の血液流入ポート46もしくは血液流入ポート46に接続されるチューブ416が貫通可能な上端側貫通部85および白血球除去器40の血液流出ポート47もしくは血液流出ポート47に接続されるチューブ417が貫通可能な下端側貫通部86を備えている。

【0062】本発明の硬質ホルダー80は、本体部82と、上端側貫通部85、下端側貫通部86を備えている。本体部82は、図5に示すように平板状部分821aを含む第1の平板部82aと平板状部分821bを含む第2の平板部82bを備えている。第1の平板部82aと第2の平板部82bは別部材で作製され、両者はほぼ同じ形状に作製されている。また、本体部82は、第1の平板部82aと第2の平板部82bとが着脱可能なように、その両側端に固定部84a、84bを有している。固定部84aは、第1の平板部82aの両側端に凹部として作製され、固定部84bは、第2の平板部82bの固定部84aに対応する位置に凸部として作製されている。そして、凹部である固定部84aと凸部である固定部84bを嵌合することにより、第1の平板部82aと第2の平板部82bとが互いに固定される。また、このような構成より使用後は、第1の平板部82aから第2の平板部82bを容易に取り外すことができる。なお、第1の平板部82aに、第2の平板部82bを固定

84bとを嵌合させ、硬質ホルダー80を作製する。
 【0068】次に、本発明の他の実施例の硬質ホルダー80の使用方法について図5を用いて説明する。まず、本体部82を開いて、第2の平板部82bに白血球除去器40を配置する。このとき、血液流入ポート46は、第2の平板部82bの上端側貫通部85を構成する部分に配置され、血液流出ポート47は、第2の平板部82bの下端側貫通部86を構成する部分に配置されている。次に、第1の平板部82aを第2の平板部に閉じ合わせ、固定部84aと固定部84bとを嵌合させ、白血球除去器40に硬質ホルダー80を装着する。硬質ホルダー80を白血球除去器40から取り外す場合は、装着方法の手順と逆の手順を行えばよい。以上より、硬質ホルダー80は、濾過前においては、白血球除去器40に容易に装着できるとともに、濾過後は白血球除去器40から容易に取り外すことができるものとなっている。以上、白血球除去器用硬質ホルダー、白血球除去器について、説明してきたが、これらの構成は、上述したものに限定されるものではない。

【0069】

【発明の効果】本発明の白血球除去器用硬質ホルダーは、軟質樹脂製袋状ハウジングと、該ハウジング内を流入側血液室と流出側血液室とに区分するように設けられた白血球除去用フィルター部材と、前記流入側血液室と連通する血液流入ポートと、前記流出側血液室と連通する血液流出ポートとを備えている白血球除去器に装着するための白血球除去器用硬質ホルダーであって、該硬質ホルダーは、前記白血球除去器を収納するための本体部を備え、該本体部は、使用時に白血球除去器と接触するほぼ平行に形成された向かい合う平板状部分を備え、該本体部の向かい合う平板状部分の間隔は、前記白血球除去器の厚み以上となっている。このため、硬質ホルダーは、軟質樹脂製のハウジングを有する白血球除去器に装着して白血球除去器の適切な濾過を可能としている。

【0070】また、本発明の白血球除去器用硬質ホルダーが、一端に設けられた白血球除去器挿入用開口部と、他端側に設けられ、前記白血球除去器の前記ポートもしくは該ポートに接続されるチューブが貫通可能な貫通部と、該貫通部から前記開口部まで延びる前記ポートもしくは該ポートに接続されたチューブの誘導用の誘導用切り欠き部を備えるものであれば、軟質樹脂製のハウジングを有する白血球除去器に容易に装着でき、使用後は白血球除去器から容易に取り外すことができる。

【図面の簡単な説明】

【図1】図1は、本発明の実施例である白血球除去器用硬質ホルダーを示す斜視図である。

【図2】図2は、本発明の他の実施例である白血球除去

器用硬質ホルダーを示す斜視図である。

【図3】図3は、本発明の他の実施例である白血球除去器用硬質ホルダーを示す斜視図である。

【図4】図4は、本発明の他の実施例である白血球除去器用硬質ホルダーを示す斜視図である。

【図5】図5は、本発明の他の実施例である白血球除去器用硬質ホルダーを示す斜視図である。

【図6】図6は、本発明の白血球除去器用硬質ホルダーに使用される白血球除去器の流出側血液室側からみた正面図である。

【図7】図7は、図6の白血球除去器の背面図である。

【図8】図8は、図6の白血球除去器のA-A線拡大断面図である。

【図9】図9は、図6の白血球除去器のB-B線断面図である。

【図10】図10は、図6に示した白血球除去器を部分剥離した状態を示す図である。

【図11】図11は、本発明の白血球除去器に使用される白血球除去用フィルター部材を示す図である。

【図12】図12は、本発明の白血球除去器用硬質ホルダーを白血球除去器に装着した状態の断面図である。

【図13】図13は、本発明の白血球除去器用硬質ホルダーに使用される他の白血球除去器の流出側血液室側からみた正面図である。

【図14】図14は、図13の白血球除去器のC-C線拡大断面図である。

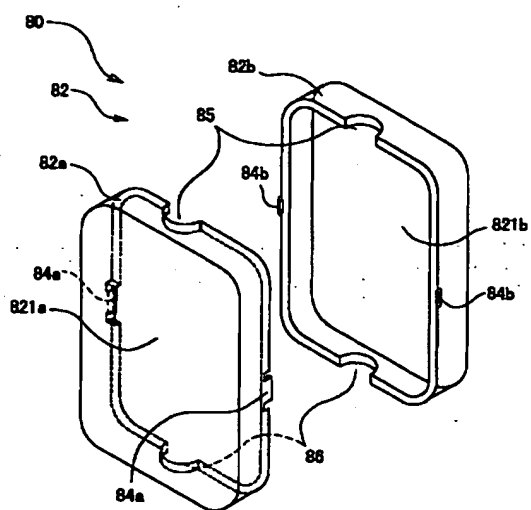
【図15】図15は、本発明の白血球除去器用硬質ホルダーに使用される他の白血球除去器を示す斜視図である。

【図16】図16は、図15に示した白血球除去器の中央断面図である。

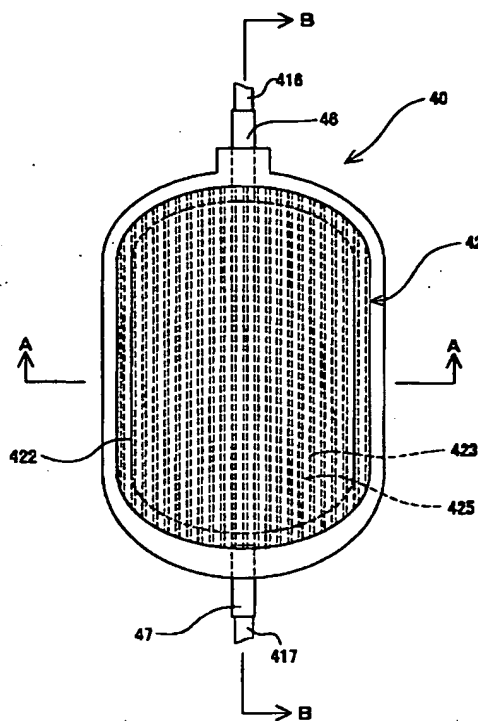
【符号の説明】

- 1 硬質ホルダー
- 10 硬質ホルダー
- 20 硬質ホルダー
- 30 硬質ホルダー
- 40 白血球除去器
- 42 軟質樹脂製ハウジング
- 43 流入側血液室
- 44 流出側血液室
- 45 白血球除去用フィルター部材
- 46 血液流入ポート
- 47 血液流出ポート
- 50 白血球除去器
- 70 白血球除去器
- 80 硬質ホルダー

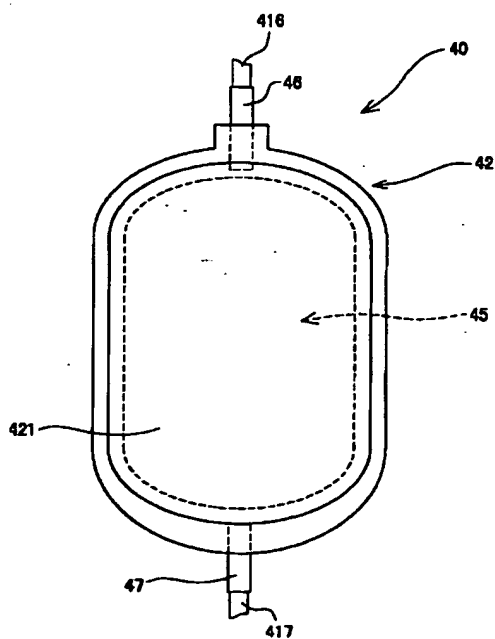
【図5】



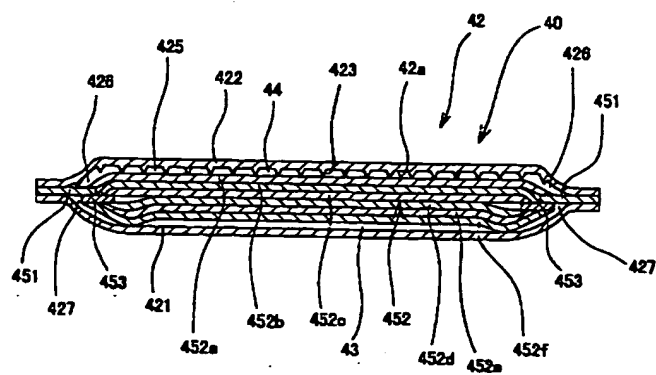
【図6】



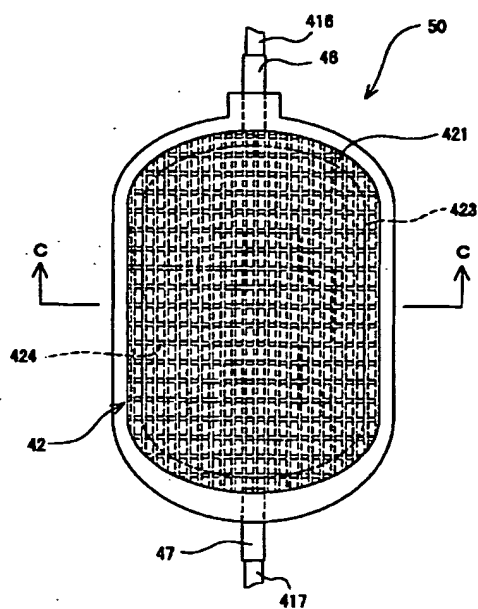
【図7】



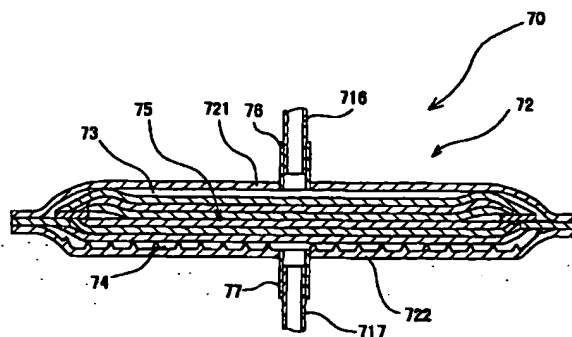
【図8】



【図13】



【図16】



(19)



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PATENT ABSTRACTS OF JAPAN

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(72) Inventor: ISHIDA NOBORU

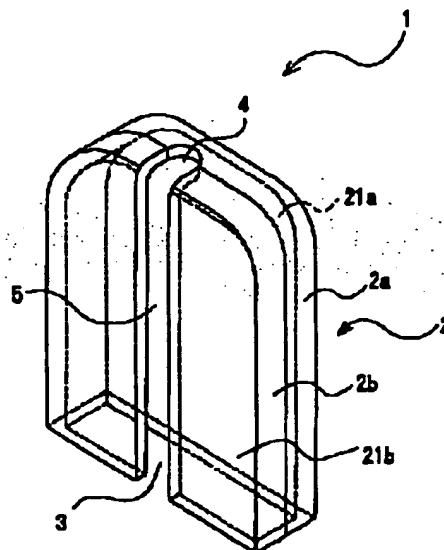
(54) HARD HOLDER FOR LEUKOCYTE REMOVER

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(57) Abstract:

PROBLEM TO BE SOLVED: To provide a hard holder to be mounted on a leukocyte remover with a housing made from a soft resin so as to enable filtering property in the leukocyte remover.

SOLUTION: The hard holder 1 is mounted on the leukocyte remover 40 provided with a bag-shaped housing 24 made from a soft resin, a filter member 5 for removing leukocytes, a port 46 for flooding bloods and a port 47 for draining bloods. In this case, the hard holder 1 is provided with a main body 2 for housing the remover 40, the main body 2 is provided with opposing planar parts 2a and 2b which come into contact with the remover when being used and are formed so as to be almost parallel with each other. The distance between the opposing planar parts 21a and 21b in the main body 2 is larger than the thickness of the remover 40 or more.



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[Abstract]

[Object] The present invention relates to provision of a hard holder which is attached on a white blood cell remover having a soft resin-made housing to enable an appropriate filtering of the white blood cell remover.

[Means for Settlement] A hard holder 1 is attached on a white blood cell remover 40 comprising a soft resin-made bag-like housing 42, a filter member 454 for white blood cells removal, a blood inlet port 46, and a blood outlet port 47. Then, the hard holder 1 comprises a main body portion 2 for housing a white blood cell remover 40. The main portion 2 comprises flat plates 2a and 2b located opposite to each other which contact the white blood cell remover at the time of usage and which are manufactured approximately in parallel to each other. An interval between the two opposite flat plates 21a and 21b in the main body portion 2 is larger than a thickness of the white blood cell remover 40.

[Claims]

[Claim 1] A hard holder for a white blood cell remover for housing the white blood cell remover comprising a soft resin-made bag-like housing, a filter member for white blood cells removal which is provided to partition an inside of the housing into a blood chamber on an inlet side and a blood chamber on an outlet side, a blood inlet port communicating with the blood chamber on an inlet side, and a blood outlet port communicating with the blood chamber on an outlet side, characterized in that the hard holder comprises a main body portion, the main body portion comprises a flat plate-like portions located opposite to each other which contact the white blood cell remover at the time of usage and which are manufactured approximately in parallel to each other, and an interval between the flat-plate like portions located opposite to each other in the main portion is larger than a thickness of the white blood cell remover.

[Claim 2] The hard holder for the white blood cell remover according to claim 1, wherein the hard holder for the white blood cell holder comprises an open portion for the insertion of the white blood cell remover which portion is provided on one end thereof, a penetration portion provided on the other end thereof to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, a guiding notch portion for guiding the port which extends from the penetration portion to the open portion or the tube connected to the port.

[Claim 3] The hard holder for the white blood cell remover according to claim 1, wherein the hard holder for the white blood cell holder is provided an open portion for the insertion of the white blood cell remover which portion is located on a side end of the flat plate-like portions located opposite

to each other, an upper end side penetration portion which is provided on an upper end side to allow the port of the white blood cell remover or the tube connected to the port to pass therethrough, a lower end side penetration portion provided on a lower end side to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, an upper end side guiding notch portion for guiding the port which extends from the upper end side penetration portion to the open portion or a tube connected to the port, and a lower end side guiding notch portion for guiding the port which extends from the upper end side penetration portion to the open portion or a tube connected to the port.

[Claim 4] The hard holder for the white blood cell remover according to claim 1, wherein the hard holder for the white blood cell remover comprises an open portion for the insertion of the white blood cell remover located at a side end of the flat plate portion located opposite to each other, an upper side penetration portion provided in the vicinity of a central portion of an upper side flat plate-like portion to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, a lower side penetration portion provided in the vicinity of a central portion of the lower side flat plate-like portion to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, an upper side guiding notch portion for guiding the port which extends from the upper side penetration portion to the open portion and a lower side guiding notch portion for guiding the port which extends from the penetration portion to the open portion or the tube connected to the port.

[Claim 5] The hard holder for the white blood cell holder according to

claim 1, wherein the main body portion comprises a first flat plate portion and a second flat plate portion which is rotatably supported on the first flat plate in a freely opening and closing manner and which becomes approximately parallel to the first flat plate portion for housing the white blood cell remover in a closed state, and furthermore, the main body portion comprises an upper end side penetration portion which allows the port of the white blood cell remover or a tube connected to the port to pass therethrough in a state in which the white blood cell remover is housed, and a lower end side penetration portion which allows the port of the white blood cell remover or a tube connected to the port to pass therethrough.

[Claim 6] The hard holder for the white blood cell remover according to claim 1, wherein the hard holder comprises a first flat plate portion and a second flat plate portion which can be attached on and detached from the first flat plate portion and which becomes approximately parallel to the first flat plate portion in an attachment state in which the white blood cell remover is housed, and furthermore, the main body portion comprises an upper end side penetration portion which allows the port of the white blood cell remover or a tube connected to the port to pass therethrough in the state in which the white blood cell remover is housed, and a lower end side penetration portion which allows the port of the white blood cell remover and the tube connected to the port to pass therethrough.

[Claim 7] The hard holder for the white blood cell remover according to any of claims 1 through 6, wherein the hard holder comprises a projection on a surface thereof.

[Claim 8] The hard holder for the white blood cell remover according

to any of claims 1 through 6, wherein the hard holder comprises a rib on an inner surface thereof.

[Claim 9] The hard holder for the white blood cell remover according to claim 7 or 8, wherein the projection or the rib is arranged in a direction in which a liquid which passes through the white blood cell remover flows.

[Detailed Description of the Invention]

[0001]

[Field of the Invention] The present invention relates to a holder for housing a white blood cell remover, and more particularly to a hard holder for housing a white blood cell remover, the holder having a housing which is made of soft resin.

[0002]

[Background of the Invention] Conventionally, there is available a white blood cell remover which comprises a housing, a filter member provided so as to partition an inside of the housing into a blood chamber on an inlet side and a blood chamber on an outlet side, a blood inlet port communicating with the blood chamber on the inlet side, and a blood outlet port communicating with the blood chamber on the outlet side. In the white blood cell remover having a housing which is manufactured of soft resin out of various types of white blood cell removers, in the case where the white blood cell remover is erroneously pressed during or after the filtering of the blood, it sometimes happen that an unnecessary substance flows out which is removed in the filtering flows out because the housing is soft.

[0003] Furthermore, in the case where a filtered substance flows into the white blood cell remover, the soft resin-made housing is swollen, and a large

amount of filtered substance is detained in the blood chamber on the inlet side. Consequently, a fall distance of the liquid in the white blood cell remover cannot be maintained with the result that it is feared that a pressure at which the filtered substance is pressed into the filtering member becomes small so that the filtering rate is slowed down. Furthermore, the Japanese Unexamined Patent Publication No. HEI 11-206875 describes a white blood cell recycling set which comprises a white blood cell remover having a housing manufactured of soft resin, and a hard housing vessel for housing the white blood cell remover. The recycling set is constituted in such a manner that the set recycles the white blood cells appropriately by regulating the capacity of the white blood cell remover through which the blood is allowed to pass, more specifically, the capacity of the blood chamber on the inlet side is regulated to appropriately recycle the white blood cells.

[0004] However, since the white blood cell recycling set described in the Japanese Unexamined Patent Publication No. HEI 11-206875 houses the hard vessel in a state in which the white blood cell remover is compressed, the soft resin-made housing and the white blood cell removal filter adheres to each other with the result that even when the blood is allowed to be filtered in the white blood cell remover, the flow of the blood in the white blood cell remover is hindered to cause the slow down of the filtering rate. In particular, in the case where the filter member is manufactured of a porous material, it is feared that the pores in the porous material is crushed when the remover is housed in the hard holder in a compressed state, so that the blood flows into the filter with more difficulty.

[0005]

[Problem to be Solved by the Invention] Since the conventional hard holder is manufactured integrally with the white blood cell remover in many cases, the volume of the product becomes larger in the state in which the hard holder is attached on the white blood cell remover than in the case of the presence of the white blood cell remover only which leads to an increase in the transportation cost. Furthermore, since the hard holder which is manufactured in advance in injection molding for each of the white blood cell remover is fixed and attached by heat fusing, attachment or screws, the attachment step becomes troublesome which leads to an increase in the transportation cost. Furthermore, since it is difficult to detach the hard holder after the hard holder is attached on the white blood cell remover in the conventional hard holder, both the hard holder and the white blood cell remover are together discarded after the filtering which has caused a problem of an increase in a garbage amount. Therefore, an object of the present invention is to provide a hard holder which enables an appropriate filtering of the white blood cell remover by attaching the hard holder on white blood cell remover having soft resin-made housing, and a hard holder which can be easily attached on the white blood cell remover having a soft resin-made housing before usage and which can be easily detached from the white blood cell remover after usage.

[0006]

[Means for Solving the Problem] The above object of the invention can be attained by a hard holder for a white blood cell remover for housing the white blood cell remover comprising a soft resin-made bag-like housing, a filter member for white blood cells removal which is provided to partition an

inside of the housing into a blood chamber on an inlet side and a blood chamber on an outlet side, a blood inlet port communicating with the blood chamber on an inlet side, and a blood outlet port communicating with the blood chamber on an outlet side. Then the hard holder is such that the main body portion comprises a flat plate-like portions located opposite to each other which contact the white blood cell remover at the time of usage and which are manufactured approximately in parallel to each other, and an interval between the flat-plate like portions located opposite to each other in the main portion is the same as or larger than a thickness of the white blood cell portion.

[0007] Then, the hard holder for the white blood cell remover preferably comprises an open portion for the insertion of the white blood cell remover which portion is provided on one end thereof, a penetration portion provided on the other end thereof to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, a guiding notch portion for guiding the port which extends from the penetration portion to the open portion or the tube connected to the port. Furthermore, the hard holder for the white blood cell remover preferably comprises an open portion for the insertion of the white blood cell remover which portion is located on a side end of the flat plate-like portions located opposite to each other which portion is located at a side end of the flat plate-like portion located opposite to each other, an upper end side penetration portion which is provided on an upper end side to allow the port of the white blood cell remover or the tube connected to the port to pass therethrough, a lower end side penetration portion provided on a lower end side to allow the port of the white blood cell

remover or a tube connected to the port to pass therethrough, an upper end side guiding notch portion for guiding the port which extends from the upper end side penetration portion to the open portion or a tube connected to the port, and an lower end side guiding notch portion for guiding the port which extends from the upper end penetration portion to the open portion or a tube connected to the port.

[0008] Furthermore, the hard holder for the white blood cell remover preferably comprises an open portion for the insertion of the white blood cell remover located at a side end of the flat plate portion located opposite to each other, an upper side penetration portion provided in the vicinity of a central portion of an upper side flat plate-like portion to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, a lower side penetration portion provided in the vicinity of a central portion of the lower side flat plate-like portion to allow the port of the white blood cell remover or a tube connected to the port to pass therethrough, an upper side guiding notch portion for guiding the port which extends from the upper side penetration portion to the open portion and a lower side guiding notch portion for guiding the port which extends from the penetration portion to the open portion or the tube connected to the port. Furthermore, the main body portion preferably comprises a first flat plate portion and a second flat plate portion which is rotatably supported on the first flat plate in a freely opening and closing manner and which becomes approximate parallel to the first flat plate portion for housing the white blood cell remover in a closed state, and furthermore, the main body portion comprises an upper end side penetration portion which allows the port of the white blood cell remover or a

tube connected to the port to pass therethrough in a state in which the white blood cell remover is housed, and a lower end side penetration portion which allows the port of the white blood cell remover or a tube connected to the port to pass therethrough. Besides, the main body portion preferably comprises a first flat plate portion and a second flat plate portion which can be attached on and detached from the first flat plate portion and which becomes approximately parallel to the first flat plate portion in an attachment state in which the white blood cell remover is housed, and furthermore, the main body portion comprises an upper end side penetration portion which allows the port of the white blood cell remover or a tube connected to the port to pass therethrough in the state in which the white blood cell remover is housed, and a lower end side penetration portion which allows the port of the white blood cell remover and the tube connected to the port to pass therethrough.

[0009] Furthermore, the hard holder preferably comprises a projection on an inner surface thereof. Furthermore, the hard holder preferably comprises a rib on an inner surface thereof. Furthermore, the projection or the rib is preferably arranged in a direction in which a liquid passing through the white blood cell remover flows.

[0010]

[Embodiments of the Invention] The hard holder for the white blood cell remover according to the present invention will be explained by using embodiments shown in the drawings. Fig. 1 is a perspective view showing a hard holder for a white blood cell remover according to an embodiment of the present invention. Fig. 6 is a front view showing the white blood cell

remover used in the hard holder for the white blood cell remover as seen from the side of the blood chamber on the inlet side. Fig. 7 is a rear surface view showing the white blood cell remover of Fig. 6. Fig. 8 is an enlarged sectional view taken long line A-A, the view showing the white blood cell remover of Fig. 6. Fig. 9 is a sectional view taken along line B-B, the view showing the white blood cell remover of Fig. 6. Fig. 10 is a view showing a state in which the white blood cell remover shown in Fig. 6 is partially peeled off. Fig. 11 is a view showing a filter member for the removal of white blood cells, the member being used in the white blood cell remover according to the present invention. Fig. 12 is a sectional view showing a state in which the hard holder for the white blood cell remover is attached on the white blood cell remover according to the embodiment of the present invention. Fig. 13 is a front view as seen from the side of the blood chamber on the outlet side of another white blood cell remover used in the white blood cell remover according to the present invention. Fig. 14 is an enlarged sectional view taken along line C-C of the white blood cell remover of Fig. 13. Incidentally, the upper side in Fig. 1, Figs. 6 through 14 is either described as "upper" or "upper end" while the lower side is described as "lower" or "lower end".

[0011] The hard holder 1 for the white blood cell remover according to the present invention is intended to be attached on the soft resin-made white blood cell remover 40. The white blood cell remover 40 comprises a soft resin-made bag-like housing 42, a filter member 45 for the white blood cells removal which is provided to partition an inside of the housing 42 into a blood chamber 43 on an inlet side and a blood chamber 44 on an outlet side, a blood inlet port 46 communicating with the blood chamber on the blood

chamber on an inlet side, and a blood outlet port 47 communicating with the blood chamber 44 on an outlet side. Then, the hard holder 1 for the white blood cell remover comprises a main body portion 2 for housing the bag-like housing 42 of the white blood cell remover 40, and the main body portion 2 comprises a flat plate-like portion located opposite to each other which contact both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover at the time of usage (at the time of blood inlet) and which are manufactured approximately in parallel to each other. An interval between the flat plate-like portions 21a and 21b located opposite to each other in the main body portion 2 becomes the same as or larger than the thickness of the white blood cell remover 40. Furthermore, the hard holder 1 for the white blood cell remover comprises an open portion 3 for the insertion of the white blood cell remover located on one end, a penetration portion 4 provided on the other end to allow the blood inlet port 46 of the white blood cell remover 40 or a tube 416 connected to the blood inlet port 46 to pass therethrough, and a guiding notch portion 5 for guiding the blood inlet port 46 which extends from the penetration portion 4 to the open portion 3 or the tube 416 connected to the blood outlet port 46.

[0012] As the white blood cell remover 40 housed in the hard holder 1 for the white blood cell remover, as shown in Figs. 6 through 9, the soft resin-made housing 42 is used which comprises two thermoplastic soft resin sheets 421 and 422, the sheet 421 being located on the side of the blood chamber 43 on the inlet side while the sheet 422 being located on the side of the blood chamber 44 on the outlet side. Then, on the inner surface 42a of the outlet side sheet 422, namely, the surface located opposite to the surface of the

blood chamber 44 on the outlet side of the filter member 45, an uneven configuration having a height difference of 0.2 to 2mm with the result that the adherence of the hard holder and the white blood cell remover is hindered even in the state in which the filter member 45 of the white blood cells removal presses against the inner surface (the inner surface 42a of the sheet 422 on the outlet side) of the soft resin-made bag-like housing 42 to secure a blood inlet channel between the filter member 45 for the white blood cells removal and the inner surface 42a (the inner surface 42a of the sheet 422 on the outlet side) of the housing thereby preventing the slow down of the filtering rate.

[0013] In this white blood cell remover 40, as shown in Figs. 6, 8, and 10, on the inner surface 42a of the sheet 422 of the blood chamber on the outlet side, a plurality of ribs 423 are manufactured which extends approximately in parallel to the other end side (for example, in a direction of the blood flow) from one end side of the housing 42. By providing such ribs 423, the adherence of the filter member 45 of the white blood cell removal and the inner surface 42a of the sheet 422 on the outlet side is prevented while an action of guiding the filtering blood to the outlet port is displayed. An interval between the plurality of ribs 423 is preferably about 1 through 5mm, so that the interval therebetween becomes approximately equal.

Furthermore, the width of the rib 423s is preferably about 0.5 through 1mm. The height of the ribs 423 (height difference) is preferably 0.2 through 2mm. The height is particularly preferably 0.5 through 1mm. Furthermore, the configuration of the rib 423 is preferably manufactured so that the configuration becomes thinner toward the end as seen in a triangular

pyramidal configuration and a hemispheric configuration.

[0014] Furthermore, like the white blood cell remover 50 according to the embodiment shown in Figs. 13 and 14, on the inner surface 42a of the sheet 422 on the outlet side a plurality of vertical ribs 423 and a plurality of horizontal ribs 424 which intersects the vertical ribs 423 approximately at a right angle may be provided. In this case, an interval between the vertical ribs 423 and the horizontal ribs 424 is preferably 1 through 5mm, and the interval therebetween is preferably equal. Besides, the width of the vertical ribs 423 and the horizontal ribs 424 is preferably 0.5 through 1mm.

Furthermore, the width of the vertical ribs 423 and the horizontal ribs 424 may be preferably about 0.5mm to 1mm. The height (height difference) of the vertical ribs 424 is preferably 0.2 through 2mm. The height is particularly preferably 0.5 through 1mm. Besides, the height (height difference) of the horizontal ribs is preferably 0.2 through 2mm, and particularly preferably 0.2 through 0.5mm. Then, preferably, the height of the horizontal ribs 424 is lower than the height of the vertical ribs 423 by about 0.3 through 1mm. Specifically, the height of the vertical ribs 424 is lower than the vertical ribs 423 by 0.3 to 1mm. Furthermore, the interval between the horizontal ribs 424 is preferably wider than the interval between the vertical ribs 423. Specifically, the interval between the horizontal ribs 424 is preferably wider than the interval between the vertical rib 423 by about 1 to 2m.

[0015] Then, in this white blood cell remover 40, the filter member 45 for the white blood cells removal comprises a thermoplastic soft resin sheet-like frame 451 and a filter function member 452 and a filter function member 452

in which a fringe portion is directly or indirectly adhered to the frame 451.

The filter function member 452 is manufactured of a lamination of a plurality of filter material. The filter member 45 for the white blood cells removal used here comprises a filter function portion manufactured by the filter function member 452 and a non-filter function portion manufactured on the whole circumference of the fringe of the filter function member. Then, the filter member 45 for the white blood cells removal is in the state of being sandwiched between two thermoplastic soft resin-made sheets.

Furthermore, the fringe portion of the filter member 45 for the white blood cells removal is heat fused to the two thermoplastic soft resin sheets. As a consequence, the filter member 45 for the white blood cells removal partitions a space (inside of the housing 42) inside of two thermoplastic soft resin-made sheets 421 and 422 into a blood chamber 43 on the inlet side and a blood chamber 44 on the outlet side. Then a soft resin-made tube constituting the blood inlet port 46 is heat fused to the central portion of the other end side (upper end side) between two thermoplastic resin tubes so as to be communicated to the blood chamber 43 on the inlet side, that is, in such a manner that an open portion on one end of the soft resin-made tube opens in the blood chamber 43 on the inlet side. In a similar manner, the soft resin-made tube constituting the blood outlet port 47 is heat fused to the central portion of the other end side (lower end side) so as to be communicated to the blood chamber 44 on the outlet side, that is, in such a manner that the open portion on one end is open in the blood chamber 44 on the outlet side.

[0016] In particular, in this white blood cell remover 40, the filter member 45

for the white blood cells removal comprises, as shown in Fig. 11, short belt-like extending portions 451a and 451b which projects in an outward direction toward the central portion on one end side (upper end side) and toward the central portion on the other end side (lower end side) thereof. The soft resin-made tube constituting the blood inlet port 46 is fused to the sheets 421 and 422 so as to be located between the extending portion 451a and the resin sheet 421 on the inlet side with the result that the blood inlet port 46 is communicated only to the blood chamber 43 on the inlet port 43 while the blood chamber outlet port 47 is communicated only to the blood chamber 44 on the outlet side. Then, to the blood inlet port 46 and the blood outlet port 47, a tube 416 for introducing the filtered substance (not shown) to the white blood cell remover and a tube 417 for exhausting a filter liquid (not shown) are connected. As a consequence, the tube 416 is communicated to the blood chamber 43 via the blood inlet port 46, and the tube 417 is communicated to the blood chamber 44 on the outlet port 47. The connection of the tubes 416 and 417, the blood inlet port 46 and the blood outlet port 47 is made by inserting the tubes 416 and 417 to the inside of the soft tube constituting the ports 416 and 417 to be fused. As a consequence, preferably, an external diameter of the tube is manufactured in approximately the same size as the internal diameter of the port. As material for forming the tube, resin is preferable which is used in the blood inlet port 46 and the blood outlet port 47. Out of such resin, resin is preferable which can be easily fused with the blood inlet port 46 and the blood outlet port 47.

[0017] Furthermore, the filter member 45 for the white blood cells removal is

fused to the housing 42 (between two thermoplastic soft resin sheets 421 and 422) at a location outside of the broken line shown in Fig. 11. As a consequence, the white blood cell remover 40 comprises a portion (that is a portion which is not provided with a filtering function, non-filtering function portion) which does not contact the filter function portion 452 and a blood flow channel 426 manufactured between the inner surface of the housing on a fringe portion of the blood chamber 44 on the outlet side. Similarly, the white blood cell remover 40 comprises a portion which does not contact the filter function portion 452, that is, the portion which is not provided with the filtering function, and a blood flow channel 427 manufactured between the non-filter function portion and the inner surfaces of the housing on the fringe portion in the housing. Thus, the flow of blood on the fringe portion inside of the housing 42 is made favorable by having the portion without such non-filter function and the blood flow channel manufactured between the inner surfaces of the housing 42 on the fringe portion in the housing thereby preventing residual blood on the fringe portion. Furthermore, with the presence of the blood flow channel in the vicinity of the blood outlet port 47 inside of the blood chamber 44 on the outlet side, the filtered blood which flows in the flow channel 425 between ribs 423 is favorably guided to the blood outlet port 47 with the result that filtering rate is further slowed down. Then, preferably, the white blood cell remover detains air of 5ml or more. As material for forming thermoplastic soft resin sheets 421 and 422 constituting the housing 42, thermoplastic soft resin sheet-like frame 451 of the filter member 45 for the white blood cells removal, the blood inlet port 46 and the blood outlet port 47, a flexible thermoplastic resin is used.

[0018] The fixing of thermoplastic resin soft resin sheets 421 and 422, thermoplastic soft resin sheet-like frame 451 of the filtering member 45 for the white blood cells removal, the blood inlet port 46 and the blood outlet port 47 are made with fusing in which no sticking agent is used. The welding may be outside heating welding by the heat seal, or an inside welding by a high frequency welder and an ultrasonic wave welder.

Furthermore, a method for welding may be such that the above members are all fused at the same time, or the members are fused step by step.

[0019] Then, the filter function portion 452 of the filtering member 45 for the white blood cells removal is manufactured of a lamination of a plurality of filter materials comprising a porous material or unwoven cloth. Specifically, six sheets of filtering material 452a, 452b, 452c, 452d, 452e, 452f are laminated. Incidentally, as a number of sheets of lamination of the filter material, two to ten sheets are preferable. Then, in the embodiment, since the number of the sheets of lamination of the filtering material is large, so that some sheets of the filter material (three to five sheets, for example) are fused to the sheet-like frame 453 for welding assistance, with the result that the outside fringe portion of the welding assistance sheet-like frame 453 on which the filtering material is fused to the inner circumferential portion of thermoplastic soft resin sheet-like frame 451. The porous material used on the filter function portion 452 refers to a liquid permeating structure with a large number of fine pores communicating from one side surface to other surfaces. As an example of pores, a porous material comprising natural, synthetic, semi-synthetic, recycled organic or inorganic fibers, a porous material having pores manufactured by welding, sintering, rolling and

drilling of pore contents, and a porous material in which organic or inorganic fine particles, and fine pieces are charged and connected can be given. Then, as the filter function portion (filter material) 452 of the filter member 45 for the white blood cells removal, particularly, a sponge-like polyurethane porous material, and a polyvinylformal porous material are preferable. Then, as a porous diameter of the porous material, the porous material having a large porous diameter is used, and either the material having a thick thickness or the material having a thin thickness may be used to be laminated. When the porous diameter is small, even the porous material having a thin thickness can be used. When the blood cells can pass the porous material, any type of the porous material can be used by appropriately selecting the porous diameter and the thickness. In particular, the porous material having an average porous diameter of 5 through $20\ \mu\text{m}$ is effective for the removal of the white blood cells.

[0020] As unwoven fabric to be used for the filter function (filter material) 452 of the filter material 45 for the white blood cells removal, the unwoven fabric having the fabric diameter of about 0.3 through $20\ \mu\text{m}$ is used. As the fabric material, the material comprising semi-synthetic fabric like synthetic fabric, recycled cellulose, natural fabric like cotton, inorganic fabric or the like is used. Out of the fabric, polyester fabric such as polyethyleneterephthalate or the like, fabric such as nylon, polypropylene, polyacrylonitrile or the like are favorably used. Furthermore, as a coating material, polymer material having a hydroxyl group such as hydroxyethylmetacrylate and polymer material having a basic nitrogen containing a functional group as seen in copolymer of

dimethylaminethyl(meta)-acrylate, hydroxylethyl(meta)-acrylate, polyurethane, abucosane or the like can be used. Then, in order to improve the passage of the blood platelets, the surface of the unwoven fabric can be coated with the hydrophilic polymer, or the surface thereof can be coated with the anti-thrombus material.

[0021] The hard holder 1 for the white blood cell remover comprises a main body portion 2, an open portion 3 for the insertion of the white blood cell remover, a penetration portion 4, and a guiding notch portion 5 as seen in the embodiment of Fig. 1. The main body portion 2 is a portion for housing a bag-like housing 42 portion of the white blood cell remover 40, and the main body is manufactured in a longer length, a wider width and a thicker thickness than the whole bag-like housing 42 portion. At the same time, the hard holder 1 can house the whole housing 42 portion. At the time of attaching the hard holder 1 on the white blood cell remover, the white blood cell remover 40 can be housed in the hard holder 1 without pressing the bag-like housing 42. Furthermore, the thickness of the inside of the hard holder 1 is manufactured approximately in the same thickness as the bag-like housing 42. Consequently, after the attachment of the hard holder 1, the white blood cell remover 40 hardly moves in the hard holder 1.

[0022] Furthermore, at the time of usage (at the time of blood-inlet), the main body portion 2 comprises flat plate-like portions 21a and 21b located opposite to each other which contact both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover 40 and which are manufactured approximately in parallel to each other. An interval between the flat plate-like portions 21a and 21b located opposite to each other in the

main body portion 2 becomes same as or larger than the white blood cell remover 40, specifically somewhat larger than the white blood cell remover 40. Here, the "thickness of the white blood cell remover 40" refers to the thickness in the natural state (at the time of non- blood-inlet) of the white blood cell remover 40. As a consequence, when the hard holder 1 is attached on the white blood cell remover 40, the soft resin-made thermoplastic sheet 421 and the filter member 45 for the white blood cell remover 40 do not adhere to each other, so that the flow of the filtered substance (blood) which flows into the inside of the white blood cell remover 40 is not hindered. Consequently, the filtering in the white blood cell remover 40 can be conducted with certitude. Incidentally, even in the case where the filtering member for the white blood cells removal is manufactured of the porous material described above, the pores in the porous material are not crushed by forming the hard holder and the white blood cell remover in the above described manner and the white blood cell remover can be housed in the hard holder with the result that the filtering can be conducted with certitude.

[0023] Furthermore, the interval between the flat plate-like portions 21a and 21b located opposite to each other in the main body portion 2 becomes thinner than the thickness of the white blood cell remover in the case where the filtered substance is passed through the white blood cell remover without attaching the hard holder. As a consequence, since a space between the filter member 45 for the white blood cell remover and thermoplastic soft resin sheet 42, that is, the capacity of the blood cell chamber 43 on the inlet side is regulated, the fall distance of the liquid (filtered substance) inside of

the white blood cell remover 40 is maintained, the pressure at which the filtered substance is pressed into the filtering material 452 is heightened and the filtering rate is improved. That is, through the usage of this hard holder 1, even at the time of the inlet of the blood, the white blood cell remover 40 can be set to a state approximate to the state (natural state, non-usage state) at the time of the non-inlet of the blood with the result that the white blood cells can be removed in a state approximate to the design. That is, the filtering rate of the white blood cell remover 40 can be adjusted by adjusting the interval between the flat plate-like portions 21a and 21b located opposite to each other in the hard holder 1. Incidentally, inside of the main body portion 2, the white blood cell remover can not be pressed from the outside at the time of usage. At the same time, as long as the interval between the flat plate-like portion located opposite to each other in the hard holder 1 is larger than the thickness of white blood cell remover and has a size which allows an appropriate regulation of the capacity of the blood chamber on the inlet side, the inside of the main body portion may be manufactured in any configuration and any size. The size of the inside of the main body portion 2 of the hard holder 1 preferably such that the interval between the flat plate-like portion located opposite to each other increases by 0 through 3mm with respect to the thickness of the white blood cell remover, the length in the longitudinal direction increases by 0 through 3mm with respect to the length of the white blood cell remover, and the length in the direction which runs at right angle with the longitudinal direction of Fig. 1 increases by 0 through 3mm with respect to the width of the white blood cell remover.

[0024] An open portion 3 for the insertion of the white blood cell remover is a

portion at which the white blood cell remover 40 is inserted into the main body portion 2, and the open portion 3 is manufactured on a lower end side (one end side) of the main body portion 2. Furthermore, since the open portion 3 is manufactured is a size not less than the area of the cross section (Fig. 8) taken along line A-A of Fig. 6. As a consequence, the white blood cell remover 40 can be inserted into the hard holder 1 from the upper end.

Incidentally, the white blood cell remover can be easily inserted by forming the vicinity of the open portion 3 into a tapered configuration.

[0025] The penetration portion 4 is a portion which allows the blood inlet port 46 of the white blood cell remover 40 or the tube 416 connected to the blood inlet port 46 to pass therethrough. Specifically, the penetration portion 4 becomes a portion at which the tube 416 connected to the blood inlet port 46 passes at the time of attaching the hard holder 1 on the white blood cell remover 40. After the hard holder 1 is attached on the white blood cell remover 46, the penetration portion 4 becomes a portion which allows the blood inlet port 46 to pass therethrough. Consequently, in the state in which the hard holder is attached as well, the filtered substance can be introduced into the inside of the white blood cell remover. Furthermore, in the embodiment, the penetration portion 4 is manufactured at a position corresponding to the blood inlet portion 46 at an upper end of the main body portion 2. The penetration portion 4 may be manufactured at any position of the blood inlet port 46 (at an upper end of Fig. 1) as long as the penetration portion 4 does not hinder the flow of the liquid in the blood inlet port 46 and the tube 41 connected to the blood inlet port 46. Furthermore, in the embodiment of the present invention, the penetration portion 4 is

manufactured in a circular configuration in the same manner as the external diameter of the port 46. The present invention is not limited thereto, and the configuration may be manufactured in an oblong configuration or the like. Furthermore, the inner diameter of the penetration portion 4 is preferably manufactured in a size of -1mm or more and 10mm or less with respect to the external diameter of the port 46. This is because even when the penetration portion 4 is narrower by about 1mm than the external diameter of the port 46, the penetration portion 4 allows the port to pass therethrough because of the softness and extendibility of the port 46. When the penetration portion 4 is larger by about 10mm than the port, the port 46 is not detached from the penetration portion 4. Incidentally, in the embodiment, in the state in which the hard holder 1 is attached on the white blood cell remover 40, the port 46 passes through the penetration portion 4, but the present invention is not limited thereto. The hard holder and the white blood cell remover may be manufactured in such a manner that the tube 416 may pass through the penetration portion 416. The inner diameter of the penetration portion in this case is preferably manufactured in a size of -1mm or more and 10mm or less with respect to the external diameter of the tube. Incidentally, in the embodiment of the present invention, the penetration portion 4 is manufactured at an upper end of the main body portion 2 while the open portion 3 is manufactured at a lower end thereof. However, the present invention is not limited thereto. An open portion for insertion may be manufactured at an upper end while the penetration may be manufactured at a lower end thereof.

[0026] The guiding notch portion 5 extends from the penetration portion 4 to

the open portion 3. At the time of attaching the hard holder on the white blood cell remover 40, the guiding notch portion 5 becomes a portion for guiding the tube 416 to the penetration portion 4. Furthermore, the notch portion 5 is manufactured in a straight line manner from the penetration portion 4 to the open portion 3 on the side of the blood chamber 44 on the outlet side of the white blood cell remover 40 in the main body portion 2. In this manner, the reason why the notch portion 5 is manufactured on the side of the blood chamber 44 on the outlet side is that when the notch portion is manufactured on the blood chamber 43 on the inlet side, the inner wall of the main body portion is expanded at the time of the expansion of the blood chamber 43 (housing 421) on the inlet side, or the housing 421 is oozed out from the notch with the result that the capacity cannot be regulated with certitude. Incidentally, the notch portion is not limited to one which is manufactured in a straight line configuration as described above. The notch portion 5 may be manufactured so that the tube 416 is not detached from the notch portion, and the tube is bent in the midst of the open portion for insertion from the penetration portion 4. Incidentally, the width of the notch portion 5 is preferably manufactured in a size of -1mm or more and +10mm or less with respect to the external diameter of the port 46 or the tube 416 for the same reason as the penetration portion 4. Incidentally, the inner diameter of the penetration portion is larger than the external diameter of the port, and the width of the notch portion is preferably manufactured in a size narrower than the external diameter of the tube. By forming the penetration portion in this manner, the tube is detached from the hard holder with difficulty while the flow of the liquid passing through

the port or the tube connected to the port is not hindered.

[0027] Furthermore, the thickness of the hard holder 1 is preferably 2mm or more at almost all the portions. This is because even with a vessel manufactured of hard resin the hard holder is pushed and spread with the expansion of the white blood cell remover when the thickness of the vessel is thin with the result that the capacity regulation cannot be appropriately regulated. Furthermore, the expression "almost all the portions" is used because even when a portion of the hard holder 1 has a thickness of less than 2mm, the above object can be attained. For example, when the thickness of the upper end portion of the hard holder 1 shown in Fig. 1 is less than 2mm, the capacity of the upper end portion of the white blood cell remover can be appropriately regulated. As formation material of the hard holder 1, polypropylene, hard vinyl chloride, polystyrene, polyethylene or the like may be used. More preferably, polypropylene is used. Incidentally, the thickness of the hard holder is preferably set to 2 to 3mm in the scope of 2mm or more.

[0028] Furthermore, the hard holder 1 is preferably provided with a plurality of projections (not shown) on an inner surface thereof. Furthermore, the hard holder 1 is preferably provided with a plurality of ribs (not shown) on an inner surface thereof. The projections and the ribs prevent the adherence of the white blood cell remover and the hard holder. As the configuration of the projection, such configuration such as conical configuration, a multilateral pyramidal configuration, and a hemispheric configuration are preferable. In particular, the hemispheric configuration is preferable. The height of the projection (height difference) is preferably set

to 0.2 through 2mm. In particular, 0.5 through 1mm is preferable.

Furthermore, the size of the bottom surface of the projection is preferably set to about 0.5 through 10mm². Furthermore, although the number of projections differs depending on the area of the bottom surface of the projection, about three to fifty projections per 1cm² and a distance between projections is preferably set to 1 through 10mm. The configuration of the ribs is preferably manufactured in a manner that the width of the configuration becomes narrower toward the tip as seen in a conic configuration and a hemispheric configuration. The interval between the ribs is preferably set to about 2 to 6mm. The ribs are arranged approximately in an equal distance. The width of ribs is preferably set to 1 to 3mm. The height of the ribs is preferably set to 1 to 3mm.

[0029] Furthermore, the hard holder 1 is preferably manufactured of resin having high transparency. As a consequence, it is possible to confirm in what state the filtered substance flows so that instant measures can be taken when the filtered substance is stuck. As resin having high transparency, styrene type resin such as polystyrene, styrenebutylene copolymer or the like and polyolefine resin such as polycarbonate, polypropylene, polyethylene or the like are used. Incidentally, when the state in the white blood cell remover can be confirmed, the resin is not be required to be completely transparent, and the resin may be manufactured of opaque resin.

[0030] Next, there will be explained a method for manufacturing the hard holder 1 according to an embodiment of the present invention. In the beginning, a surface side member 2a including the flat plate-like portion 21a

of the hard holder 1 and the rear side member 2b including the flat plate-like portion 21b are separately injection molded. Next, the side for housing the white blood cell remover 40 of the surface side member 2a and the side for housing the white blood cell remover 40 of the rear side surface member 2b are directed in an inward direction so that the both side are arranged to be opposite to each other and both fringes are joined with the result that the hard holder can be manufactured. Joining of the fringe portions is conducted by a high frequency welder, and inside welding by the ultrasonic wave welder. Screw holes are provided on one or both of the surface side member or the rear surface side member to be joined by screwing.

[0031] Next, a method for using the hard holder 1 according to the embodiment of the present invention will be explained. In the beginning, the white blood cell remover 40 is arranged below the hard holder 1 in the state in which the blood inlet port 46 is placed above. Thereafter, the tube 416 connected to the blood inlet port 46 is fit into the notch portion 5 to guide the tube 416 to the penetration portion 4. In this state, the white blood cell remover 40 is arranged immediately under the open portion 3 for the insertion while the tube 416 on the side of the blood inlet port 46 passes through the penetration portion 4 to be located on the inside of the main body portion 2. Next, in the state in which the white blood cell remover 40 is fixed, the hard holder 1 is moved in a downward direction, the white blood cell remover 40 is inserted from the open portion 3 for the insertion, and the hard holder 1 is attached on the white blood cell remover 40. On the other hand, in the case where the hard holder 1 is detached from the white blood cell remover 40, a procedure in the attachment method may be conducted in

a reverse order. Through such step, the hard holder 1 can be easily attached on the white blood cell remover 40 before filtering and the hard holder 1 can be easily detached from the white blood cell remover 40 after filtering.

[0032] Next, the hard holder for the white blood cell remover according to another embodiment of the present invention will be explained. Fig. 2 is a perspective view showing the hard holder 1 for the white blood cell remover according to another embodiment of the present invention. The hard holder 10 for the white blood cell holder according to the embodiment comprises a main body portion 12 for housing a bag-like housing 42 portion for the white blood cell remover, and the main body portion 12 comprises flat plate-like portions 121a and 121b located opposite to each other which contact both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover 40 at the time of usage and which are manufactured approximately in parallel to each other. An interval between the flat plate-like portions 121a and 121b located opposite to each other in the main body portion 2 becomes thicker than the thickness of the white blood cell remover 40.

Furthermore, the hard holder 1 for the white blood cell remover 40 comprises an open portion 13 for the insertion of the white blood cell remover located on the side end of the flat plate-like portions 121a and 121b located opposite to each other, an upper end side penetration portion 14 provided on an upper end to allow the blood inlet port 46 of the white blood cell remover 40 and the tube connected to the blood inlet port 46 to pass therethrough, and a lower end penetration portion 15 provided on a lower end to allow the blood output port 47 of the white blood cell remover 40 and the tube 417 connected to the

blood outlet port 47 of the white blood cell remover to pass therethrough, an upper side guiding notch portion 16 for guiding the blood inlet port 46 which extends from the upper side penetration portion 14 to the open portion 13 and a lower side guiding notch portion 17 for guiding the blood outlet port 47 which extends from the penetration portion to the open portion 13 or the tube 417 connected to the port.

[0033] In the white blood cell remover of the present invention, the above white blood cell remover 40 is used. The hard holder 10 for the white blood cell remover comprises a main body portion 12, an open portion 13 for insertion, an upper end side penetration portion 14, a lower end side penetration portion 15, an upper end side guiding notch portion 16, and a lower end side guiding notch portion 17. The main body portion 12 is a portion for housing a bag-like housing 42 portion of the white blood cell remover 40 inside thereof. The main body portion 12 is a portion which is manufactured larger than the bag-like housing 42 portion in length, width and thickness. As a consequence, the hard holder 10 is capable of housing the whole bag-like housing 42 portion. As a consequence, at the time of the attachment of the hard holder 10, the white blood cell remover 40 can be housed without pressing the bag-like housing 42. Furthermore, the thickness of the inside of the hard holder 10 is manufactured approximately in the same configuration as the thickness of the bag-like housing 42. Thus, after the attachment of the hard holder 10, the white blood cell remover hardly moves in the hard holder 10. Furthermore, the side located opposite to the open portion 3 for the insertion of the main body portion 12 is manufactured into a semi-cylindrical configuration so that the hard holder

10 can be held at the time of attaching the hard holder 1.

[0034] Furthermore, the main body portion 12 comprises the flat plate-like portions which contact both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover 40 at the time of the usage in the same manner as the main body portion 2 of the hard holder 1 according to the embodiment described above. An interval between the flat plate-like portions 121a and 121b located opposite to each other in the main body portion 2 becomes the same as or thicker than the thickness of the white blood cell remover 40. Furthermore, in the same manner as the main body 2, the interval between the flat plate-like portions 121a and 121b located opposite to each other in the main body portion 12 becomes thinner than the thickness of the thickness of the white blood cell remover in the case where the filtered substance is allowed to pass through the white blood cell remover without attaching the hard holder. Incidentally, the filtering rate of the white blood cell remover 40 can be adjusted by adjusting an interval between the flat plate-like portions 121a and 121b located opposite to each other in the hard holder 10. Incidentally, the inside of the main body portion 12 cannot press the white blood cell remover from the outside at the time of usage. At the same time, as long as the interval between the flat plate-like portions located opposite to each other in the hard holder becomes the same as or larger than the thickness of the white blood cell and appropriately regulates the capacity of the blood chamber on the inlet side, the hard holder may be manufactured in any configuration and any size. The size of the inside of the main body portion 12 of the hard holder 10 is preferably such that the interval between the flat plate-like portions 121a and 121b located

opposite to each other increases by 0 to 3mm with respect to the thickness of the white blood cell remover, the length of the longitudinal direction of Fig. 2 increases by 0 to 3mm with respect to the width of the white blood cell remover, and the length in a direction which runs at right angle with the longitudinal direction of Fig. 2 increases by 0 to 3mm with respect to the width of the white blood cell remover.

[0035] The open portion 13 for insertion is a portion for inserting the white blood cell remover 40 into the main body portion 12, and is manufactured on the side end of the flat plate-like portions 121a and 121b located opposite to each other. Furthermore, since the open portion 13 is manufactured in a size not less than the area of the cross section (Fig. 9) taken along line B-B of the white blood cell remover 40 of Fig. 6, the white blood cell remover 40 can be inserted into the hard holder 10 from the side of the side surface.

Incidentally, in the same manner as the hard holder 1, a portion in the vicinity of the open portion of the open portion 13 for insertion may be manufactured to be expanded toward the open end in a tapered configuration.

[0036] The upper end side penetration portion 14 is a portion provided on an upper end of the main body portion 12 to allow the blood inlet port 46 of the white blood cell remover 40 to pass therethrough. The lower end side penetration portion 15 is a portion provided on a lower end of the main body portion 12 to allow the blood outlet port 47 of the white blood cell remover 40 to therethrough. As a consequence, even in the state in which the hard holder 10 is attached on the white blood cell remover 40 as well, the white blood cell remover 40 can conduct filtering. Furthermore, in the

embodiment, the upper end penetration portion 14 is manufactured at a location corresponding to the blood inlet port 46 of the main body portion 12 while the lower end penetration portion 15 is manufactured at a location corresponding to the blood outlet port 47 of the main body portion 12. As long as the upper end side penetration portion 14 and the lower end side penetration portion 15 do not hinder the flow of the liquid passing through the blood inlet port 46 and the blood outlet port 47 as well as the tubes 416 and 417 connected to the blood inlet port 46 and the blood outlet port 47 respectively, the upper end side penetration portion 14 and the lower end side penetration portion 15 may be manufactured at any location of the upper end side (side of the blood inlet port 46) and of the lower end side (side of the blood outlet port 47). Furthermore, although in this embodiment the upper side penetration portion 14 and the lower end side portion 15 are manufactured in a circular configuration which is the same as the external diameter of the port 46 and the port 47, the penetration portions 14 and 15 may be manufactured in an oblong configuration. Incidentally, preferably, the size of the inner diameter of the penetration portions 14 and 15 is set to -1mm or more and $+10\text{mm}$ or less with respect to the external diameter of the port in the same manner as the hard holder 1. Furthermore, in the embodiment, in the state in which the hard holder 1 is attached on the white blood cell remover 40, the port 46 passes through the upper end side penetration portion 14 while the port 47 passes through the lower end side penetration portion 15. However, the invention is not limited thereto. The tube 416 may pass through the upper end side penetration portion 14 while the tube 417 may pass through the lower end side penetration portion 15.

The inner diameter of the penetration portion is preferably manufactured in a size of -1mm or more and +10mm or less with respect to the external diameter of the tube.

[0037] The upper end side guiding notch portion 16 is a portion for guiding the blood inlet port 46 or the tube 416 from the open portion 13 to the upper end penetration portion 14 while the lower end side guiding notch portion 17 becomes a portion for guiding the blood outlet port 47 or the tube 417 from the open portion 13 to the lower end side penetration portion 15.

Incidentally, in the embodiment, the notch portions 16 and 17 are manufactured in a straight line from the upper end side penetration portion 14 and the lower end side penetration portion 15 to the open portion 13 for the insertion. However, the invention is not limited thereto. The notch portions 16 and 17 may be bent in the midst, so that the tube is detached from the hard holder 1 with difficulty. The widths of the notch portions 16 and 17 are preferably manufactured in a size of -1mm or more and +10mm or less with respect to the external diameter of the port or the tube in the same manner as the case of the upper end penetration portion 14 and the lower end penetration portion 15.

[0038] Incidentally, preferably, the internal diameter of the penetration portion is manufactured in a width wider than the external diameter of the port while the width of the notch is preferably manufactured in a size narrower than the external diameter of the tube. The port is detached from the hard holder with difficulty by manufacturing the port and the notch in this manner while the hard penetration portion does not hinder the flow of the liquid passing through the port and the tube connected to the port.

Furthermore, preferably, the thickness of the hard holder 10 is set to 2mm or more at almost all the portions in the same manner as the case of the hard holder 1. As the formation material of the hard holder, the material same as the hard holder 10 is used. Incidentally, the thickness of the hard holder 10 is preferably 2 to 3mm out of the scope of 2mm or more. Furthermore, the hard holder 10 is preferably provided with a plurality of projections (not shown) inside thereof in the same manner as the hard holder 1.

Furthermore, the hard holder 10 comprises a plurality of ribs (not shown) in the same manner as the hard holder 1. Incidentally, the size and the configuration of the projections and the ribs are preferably the same as the hard holder 1. Furthermore, the hard holder 1 is preferably manufactured of a highly transparent resin in the same manner as the hard holder 1. As a highly transparent resin, the resin same as the resin of the hard holder 1 is preferable. Incidentally, when it is possible to confirm the state in the white blood cell remover, the resin is not required to be completely transparent.

The hard holder 1 may be manufactured of opaque resin.

[0039] Next, there will be explained a method for manufacturing a hard holder 10 according to the present invention. In the beginning, a surface side member 12a including the flat plate-like portion 121a and a rear side surface member 12b including the flat plate-like portion 121b are separately injection molded. Next, the side for housing the white blood cell remover 40 of the surface side member 12a and the side for housing the white blood cell remover 40 of the rear surface member 12b are arranged opposite to each other to be directed in a downward direction and mutual fringes are joined to each other with the result that the hard holder 10 can be manufactured.

Joining is conducted in the same method as the hard holder 1.

[0040] Next, there will be explained a method for using the hard holder 10 according to another embodiment of the present invention. In the beginning, the side of the side surface of the white blood cell remover 40 is inserted from the open portion 13 for insertion which is manufactured on the side surface of the hard holder 1 to house the whole white blood cell remover 40 into the hard holder 10. In this case, the blood inlet port 46 passes through the notch portion 16 from the open portion 13 for insertion to be guided to the upper end side penetration portion 13. Similarly, the blood outlet port 47 passes through the notch portion 17 from the open portion 13 for insertion to be guided to the lower end side penetration portion 15. In the case where the hard holder 10 is detached from the white blood cell remover 40, the procedure of the attachment method may be reversed.

Through such procedure, the hard holder 10 can be easily attached on the white blood cell remover 40 before filtering while the hard holder 10 can be easily detached from the white blood cell remover 40 after filtering.

[0041] Next, the hard holder 1 for the white blood cell remover according to another embodiment of the present invention will be explained. Fig. 3 is a perspective view showing a hard holder for the white blood cell remover according to another embodiment of the present invention. Fig. 15 is a perspective view showing the white blood cell remover housing in the hard holder for the white blood cell remover. Fig. 16 is a central sectional view showing the white blood cell remover shown in Fig. 15. The hard holder 20 for the white blood cell remover according to this embodiment is intended to be attached on the white blood cell remover 70 which comprises a soft resin-

made bag-like housing 72, a filter member 75 for the white blood cells removal which partitions an inside of the housing 72 into the blood chamber 73 on the inlet side and the blood chamber 74 on the outlet side, a blood inlet port 76 communicating with the blood chamber 73 on the inlet side, and the blood outlet port 77 provided on the other side of the housing 72 and communicating with the blood chamber 74 on he blood chamber 74 on the outlet side. Then, the hard holder 20 comprises the main body portion 22 for housing the bag-like housing 72 of the white blood cell remover 70. The main body portion 22 comprises the flat plate-like portions 221a and 221b which contact the white blood cell remover at the time of usage and which are manufactured approximately in parallel to each other. An interval between the flat plate-like portions 221a and 221b located opposite to each other of the main body portion 22 is the same as or larger than the thickness of the white blood cell remover 70. Furthermore, the hard holder 20 comprises an open portion 23 for the insertion of the white blood cell remover 70 located at a side end of the flat plate-like portion 221a and 221b located opposite to each other, an upper side penetration portion 24 provided in the vicinity of a central portion of an upper side flat plate-like portion to allow the blood inlet port 76 of the white blood cell remover 70 or a tube 716 connected to the blood inlet port to pass therethrough, a lower side penetration portion 25 provided in the vicinity of a central portion of the lower side flat plate-like portion 221b to allow the blood outlet port 77 of the white blood cell remover 70 or a tube 717 connected to the blood outlet port 77 to pass therethrough, an upper side guiding notch portion 26 for guiding the blood inlet port 76 which extends from the upper side penetration portion

24 to the open portion 23 and a lower side guiding notch portion 27 for guiding the blood outlet port 77 which extends from the lower side penetration portion 25 to the open portion 23 or the tube 717 connected to the port.

[0042] A basic structure of the white blood cell remover 70 is such that the blood inlet port 76 is provided in the vicinity of the central portion of the housing 72 on the blood inlet side, and the blood outlet port 77 is provided is provided in the vicinity of the central portion of the housing 72 on the blood outlet side. Furthermore, except for the fact that external diameter is manufactured into a disc-like configuration, the basic structure of the white blood cell remover 70 is approximately the same as the basic structure of the white blood cell remover 40. Consequently, an explanation will be made centering on the different points. In the white blood cell remover 70, in the vicinity of the central portion of thermoplastic soft resin sheet 721 constituting the blood chamber 73 a hole having approximately the same size as the external diameter on one end of the tube is manufactured so that the open portion on one end of the soft resin-made tube constituting the blood inlet port 76 is opened inside of the blood chamber 73 on the inlet side. One end of the soft resin-made tube is inserted so that the soft resin-made tube runs approximately at right angle with the surface of the filtering member 75 for the white blood cells removal and the tube and thermoplastic soft resin sheet 721 are heat fused so that the white blood cell remover 70 is manufactured. Similarly, a hole having approximately the same size as the external diameter of one end of the tube is manufactured in the vicinity of the central portion of thermoplastic soft resin sheet 722 constituting the

white blood chamber 74 on the outlet side so that the open portion on one end of the soft resin-made tube constituting the blood outlet port 77 opens inside of the blood chamber 74 on the outlet side, one end of the tube is inserted so as to run approximately at right angle with the surface of the filtering member 75 for the white blood cells removal and the tube and thermoplastic resin sheet 722 are heat fused with the result that the white blood cell remover 70 9 is manufactured. Incidentally, the heat fusing is conducted in the above method.

[0043] As shown in Fig. 3, the hard holder 20 according to the embodiment of the present invention comprises the main body portion 22, an open portion 23 for the insertion of the white blood cell remover, an upper side penetration portion 24, a lower side penetration portion 25, an upper side guiding notch portion 26 and a lower side guiding notch portion 27. The main body portion 22 is a portion for housing the bag-like housing 72 portion inside. The main body portion 22 is manufactured in a size larger than the bag-like housing portion in length, width and thickness. As a consequence, the hard holder 1 can house the whole housing 72 portion. At the time of the attachment of the hard holder 1, the hard holder 1 can house the white blood cell remover 70 without pressing the bag-like housing 72. Since the thickness of the inside of the hard holder 20 is manufactured approximately in the same configuration as the thickness of the bag-like housing 72, the white blood cell remover 70 hardly moves in the hard holder 1.

[0044] In the same manner as the main body portion 2, the main body portion 22 comprises the flat plate-like portions 221a and 221b which contact both surfaces of the soft resin-made bag-like housing 72 of the white blood

cell remover at the time of usage and which are manufactured approximately in parallel to each other, and an interval between the flat plate-like portions 221a and 221b located opposite to each other of the main body portion 22 becomes the same as or larger than the thickness of the white blood cell remover 70. Furthermore, in the same manner as the main body portion 2, the interval between the flat plate-like portions 221a and 221b located opposite to each other of the main body portion 22 becomes thinner than the thickness of the thickness of the white blood cell remover in the case where the filtered substance is allowed to pass through the white blood cell remover without attaching the hard holder 20. Incidentally, the filtering rate of the white blood cell remover can be adjusted by adjusting the interval between the flat plate-like portions 221a and 221b located opposite to each other of the main body portion 22. Incidentally, the inside of the main body portion 22 cannot press the white blood cell remover from the outside at the time of usage. The interval between the flat plate-like portions located opposite to each other of the hard holder 20 may be manufactured in any size and any configuration as long as the interval has a thickness same as or larger than the thickness of the white blood cell remover and the interval appropriately regulates the capacity of the blood chamber on the inlet size. The size of the inside of the main body portion 22 of the hard holder 221a and 221b is preferably such that the interval between the flat plate-like portions 221a and 221b located opposite to each of the main body portion 22 increases by 0 to 3mm with respect to the thickness of the white blood cell remover, the interval increases by 0 to 3mm with respect to the diameter of the white blood cell remover, and the length in the direction which runs at right angle

with the longitudinal direction of the Fig. 3 increases by 0 to 3mm with respect to the diameter of the white blood cell remover..

[0045] The open portion 23 for the insertion of the white blood cell remover is a portion for inserting the white blood cell remover 70 into the main body portion 22, and is manufactured on a side end of the flat plate-like portions 221a and 221b located opposite to each other. Furthermore, the open portion 23 is manufactured in a size not less than the cross section area of the central sectional view (Fig.16) of the white blood cell remover 70 of Fig. 15. Consequently, the white blood cell remover 70 can be inserted into the hard holder 20 from the side surface side. Incidentally, in the same manner as the hard holder 20, the vicinity of the open portion of the open portion of the open portion for insertion is manufactured so as to be enlarged toward an open end in a tapered configuration.

[0046] The upper side penetration portion 24 is provided on a location corresponding to the blood inlet port 76 of the central portion of the upper side flat plate-like portion 221a in the main body portion 22. In the state in which the white blood cell remover 70 is housed in the hard holder 20, the blood inlet port 76 becomes a portion which allows the blood inlet port 76 to pass therethrough. On the other hand, in the state in which the lower side penetration portion 25 is provided at a location corresponding to the blood outlet port of the central portion of the lower side flat plate-like portion 221b of the main body portion 22 and the white blood cell remover 70 is housed in the hard holder, the lower side penetration portion 25 allows the blood outlet port 77 to pass therethrough. Incidentally, the location where the upper side penetration portion 24 and the lower side penetration portion 25 are

manufactured is not limited to what has been described above. As long as the lower side penetration portion 24 and the lower side penetration portion 25 do not hinder the flow of the liquid passing through the blood inlet port 76 and the blood outlet port 77 as well as tubes 716 and 717 connected to the blood inlet port 76 and the blood outlet port 77 respectively, the upper side penetration portion 24 and the lower side penetration portion 25 may be manufactured at any location of the upper side flat plate-like portion 221a (the side of the blood inlet port 76) of the main body portion 22 and the lower side flat plate-like portion 221b (the side of the blood outlet port 77) of the main body portion 22. Furthermore, although in this embodiment the size of the inner diameter of the upper side penetration portion 24 and the lower side penetration portion 25 are manufactured is a circular configuration in the same manner as the external diameter of the 76 and the port 77, the upper side penetration portion 24 and the lower side penetration portion 25 may be manufactured in an oblong-like configuration. Furthermore, preferably, the inner diameter of the upper side penetration portion 24 and the lower side penetration portion 25 is set to -1mm or more and +10mm or less with respect to the external diameter of the ports in the same manner as the hard holder 10. Incidentally, in this embodiment, in the state in which the hard holder is attached on the white blood cell remover 70, the port 76 passes through the upper side penetration portion 24 and the port 77 passes through the lower side penetration portion 25. The invention is not limited thereto. The tube 716 may pass through the upper side penetration portion 24 while the tube 717 may pass through the lower side penetration portion 25. The inner diameter in this case is preferably manufactured is a size of -

1mm or more and +10mm or less with respect to the external diameter of the tube.

[0047] Furthermore, the hard holder 20 comprises an upper side guiding notch portion 26 for guiding the blood inlet port 76 which extends from the upper side penetration portion 24 to the open portion 23 and a lower side guiding notch portion 27 for guiding the blood outlet port 77 which extends from the lower side penetration portion 25 to the open portion 23.

Furthermore, in this embodiment, the notch portions 26 and 27 are manufactured in a straight line configuration from the upper side penetration portion 24 and the lower side penetration portion 25 to the open portion 23 for insertion respectively. However, the invention is not limited thereto. The tube may be bent in the midst so that the tube is detached from the hard holder with difficulty. Furthermore, preferably, the width of the notch portions 26 and 27 is manufactured within -1mm or more and +10mm or less with respect to the external diameters of the port and the tube in the same manner as the case of the upper side penetration portion 24 and the lower side penetration portion 25.

[0048] Incidentally, an internal diameter of the penetration portion is wider than the external diameter of the port, and the width of the notch portion is preferably manufactured in a size narrower than the external diameter of the tube. By manufacturing the notch portion in this manner, the port is detached from the hard holder with difficulty. Furthermore, the thickness of the hard holder 20 is preferably set to 2mm or more almost at all the portions in the same manner as the case of the hard holder 1. As a formation material of the hard holder 20, the material same as the hard

holder 1 is used. Incidentally, the thickness of the hard holder 20 is preferably 2 through 3mm out of the scope of 2mm or more.

[0049] Furthermore, preferably, the hard holder 20 comprises a plurality of projections (not shown) on the inner surface in the same manner as the hard holder 1. Furthermore, preferably, the hard holder 20 comprises a plurality of ribs (not shown) in the same manner as the hard holder 1. Incidentally, preferably, the configuration and the size of the projections and ribs are the same as the hard holder 1. Furthermore, preferably, the hard holder 20 is manufactured of transparent resin in the same manner as the hard holder 1. As the transparent resin, preferably, the resin same as the hard holder 1 is preferable. Incidentally, when it is possible to confirm the state in the white blood cell remover, the resin is not required to be completely transparent. The hard holder 1 may be manufactured of an opaque resin.

[0050] Next, a method for forming the hard holder 20 according to the embodiment of the present invention will be explained. In the beginning, with respect to the hard holder 20, the surface side member 22a including the upper side flat plate-like portion 221a and the rear side member 22b including the lower side flat plate-like portion 221b are separately injection molded. Next, the hard holder is manufactured by arranging the side for housing the white blood cell remover of the surface side member 22a and the side for housing the white blood cell remover of the rear side member 22b so as to be directed in an inward direction and joining the fringe portion to each other. Joining is made in the above method.

[0051] Next, a method for using the hard holder 20 according to the embodiment of the present invention will be explained. In the beginning,

the white blood cell remover 70 is inserted from the open portion 23 for insertion which is manufactured from the side surface side of the white blood cell remover 70 to the side surface of the hard holder 20 to house the whole white blood cell remover 1. At this time, the blood inlet port 76 passes through the notch portion 26 from the open portion for the insertion to be guided to the upper side penetration portion 24. Similarly, the blood outlet port 77 passes through the notch portion 27 from the open portion 23 for the insertion to be guided to the lower side penetration portion 25. In the case where the hard holder 20 is detached from the white blood cell remover 70, the procedure is reversed from the procedure in the attachment method. Through such procedure, the hard holder 20 can be easily attached before filtering, and can be easily removed from the white blood cell remover 70 after filtering.

[0052] Next, there will be explained a hard holder 30 for the white blood cells removal according to another embodiment of the present invention. Fig. 4 is a perspective view showing the hard holder 3 for the white blood cells removal according to another embodiment of the present invention. The hard holder 30 for the white blood cell remover according to this embodiment comprises a main body portion 32 for housing the bag-like housing 42 of the white blood cell remover 40, and the main body portion 32 comprises the flat plate-like portions 321a and 321b which contacts both surfaces of the soft resin-made bag-like housing 42 and which are manufactured approximately in parallel to each other. An interval between the flat plate-like portions 321a and 321b located opposite to each other of the main body portion 22 becomes the same as or more than the thickness of the white blood cell

remover 40. Furthermore, the main body portion 32 is rotatably on the first flat plate portion 32a and the second flat plate portion 32b in a freely opening and closing manner while the main body portion 32 comprises the first flat plate 32a and the second flat plate 32b which is approximately parallel to the second flat plate 32a in a closed state in which the white blood cell remover 40 is housed. Furthermore, the main body portion 32 comprises the upper end side penetration portion 35 which allows the blood inlet port 46 of the white blood cell remover 40 or the tube connected to the blood inlet port 46 to pass therethrough, and the lower end side penetration portion 36 which allows the blood outlet port 47 of the white blood cell remover 47 and the tube 417 connected to the blood outlet port 47 to pass therethrough.

[0053] In the white blood cell remover according to the present invention, the white blood cell remover 40 is used. The hard holder 30 according to the present invention comprises the main body portion 2, the upper end side penetration portion 35, and the lower end side penetration portion 36. The main body portion 32 comprises the first plate portion 32a including the flat plate-like portion 321a and the second plate portion 32b including the flat plate-like portion 321b. The first plate portion 32a and the second plate portion 32b are manufactured in an approximately the same configuration. Furthermore, a projection 33a manufactured on an upper and a lower end of the side end of the first plate portion 32a is fit into a recessed portion 33b manufactured on an upper end and a lower end of the side end of the first plate portion 32a inside thereof with the result that the first flat plate and the second flat plate are rotatably supported so that the two plates can be

freely opened and closed. Incidentally, the structure of the main body portion 32 is not limited to what has been described above. For example, the main body portion is integrally manufactured so that the thickness at the side end of the main body portion becomes thin with the result that the first flat plate and the second flat plate can be freely opened and closed.

[0054] Furthermore, in the state (closed state) in which the first flat plate 32a and the second flat plate 32b are closed, the flat plate-like portion 321a and the flat plate-like portion 321b becomes parallel to each other. Inside of the main body portion 32, a space for housing the white blood cell remover 40 is manufactured. The internal size of the main body portion in the closed state preferably has a size enough for housing the white blood cell remover 40. Furthermore, the main body portion 32 comprises flat plate-like portions 321a and 321b located opposite to each other which contact both surfaces of the soft resin-made bag-like housing of the white blood cell remover 40 at the time of the usage (in the closed state), and the interval between the flat plate-like portions 321a and 321b located opposite to each other of the main body portion 32 is the same as or more than the thickness of the white blood cell remover 40. Furthermore, the interval between the flat plate-like portions 321a and 321b located opposite to each other of the main body portion 32 becomes thinner than the thickness of the white blood cell remover in the case where the filtered substance is allowed to pass through the white blood cell remover without attaching the hard holder in the same manner as the main body portion 2.

[0055] Incidentally, the filtering rate can be adjusted by adjusting the interval between the flat plate-like portions 321a and 321b located opposite

to each other of the hard holder 30. Incidentally, the inside of the main body portion 32 cannot press the white blood cell remover from the outside at the time of usage. Besides, when the interval between the flat plate-like portions located opposite to each other of the hard holder appropriately is the same as or more than the thickness of the white blood cell remover and appropriately regulates the capacity of the blood chamber on the inlet side, the inside of the main body portion may be manufactured in any size and any configuration. Preferably, the size of the inside of the main body of the main body portion 32 of the hard holder 30 is such that the interval between the flat plate-like portions 321a and 321b located opposite to each other increases by 0 to 3mm with respect to the thickness of the white blood cell remover, the length in a direction which runs at right angle with the longitudinal direction increases by 0 to 3mm with respect to the length of the white blood cell remover, and the length in a direction which runs at right angle with the longitudinal direction of Fig. 4 increases by 0 to 3mm with respect to the width of the white blood cell remover. Furthermore, the main body portion 32 comprises an upper end side penetration portion 35 which allows the blood inlet port 46 of the white blood cell remover 40 to pass therethrough on an upper end, and a lower end side penetration portion 36 which allows the blood outlet port 47 of the white blood cell remover 40 to pass therethrough on a lower end. As a consequence, even in the state in which the hard holder 30 is attached on the white blood cell remover 40, filtering can be conducted with the white blood cell remover 40.

[0056] The upper end side penetration portion 35 is manufactured as one circle with the overlapping of the semi-circle manufactured on the first flat

plate portion 32a and the semi-circle manufactured on the second flat plate portion 32b. Similarly, one circle is manufactured on the lower end side penetration portion 36. Incidentally, in the embodiment, the upper end side penetration portion 35 and the lower end side penetration portion 36 are manufactured in a circular configuration but may be manufactured in an oblong configuration. Incidentally, in the embodiment, the upper end side penetration portion 35 is provided on a location corresponding to the corresponding to the blood inlet port 46 of the main body portion 32 while the lower end side penetration portion 36 is provided on a location corresponding to the blood outlet port 47 on the lower end side. However, the invention is not limited thereto. As long as the upper end side penetration portion 35 and the lower end side penetration portion hinders the flow of the liquid passing through the blood inlet port 46 of the main body portion 32 or the tube 416 connected to the blood inlet port 46, and the blood outlet port 47 or the tube 417 connected to the blood outlet port 47, the upper end side penetration portion 46 and the lower end side penetration portion 47 may be manufactured on any location on the lower end side of the main body portion 32 (side of the blood inlet port 46), on the lower end side of the main body portion 32 (side of the blood outlet port 47). Furthermore, the size of the internal diameters of the upper end side penetration portion 35 and the lower end side penetration portion 36 is preferably -1mm or more or +10mm or less with respect to the ports in the same manner as the hard holder 20. Incidentally, the embodiment, in the state in which the hard holder is attached on the white blood cell remover 40, the port 46 passes through the upper end side penetration portion 35 while the port 47 passes through the

lower end side penetration portion 36. However, the present invention is not limited thereto. The tube 416 may pass through the upper end side penetration portion 35 while the tube 417 may pass through the lower end side penetration portion 36. The internal diameter of the penetration portion in this case is preferably manufactured in a size of -1mm or more and +10mm or less with respect to the external diameter of the tube.

[0057] Furthermore, the main body portion 32 is fixed in a closed state by fitting the fixing projection portion 34b provided on the side end on the opposite side of the portion rotatably supported by the first flat portion 32a into the fixing recessed portion 34a provided on the side end opposite to the portion rotatably supported by the second flat plate portion 32b. With such constitution, the second plate portion can be easily detached from the first plate portion after the usage. Incidentally the method for the attachment of the first plate portion and the second plate portion of the main portion 32 is not limited to what has been described above.

[0058] Furthermore, preferably the thickness of the hard holder 30 is 2mm or more at almost all portions in the same manner as the case of the hard holder 1. As the formation material of the hard holder, the material same as the hard holder 1 is used. Incidentally, the thickness of the hard holder 30 is preferably 2 to 3mm out of the scope of 2mm or more. Furthermore, the hard holder 30 is preferably provided with a plurality of projections (not shown) on the inner surface thereof. Furthermore, the hard holder 30 is preferably provided with a plurality of ribs (not shown) in the same manner as the hard holder 1. Incidentally, preferably, the configurations and the sizes of the projections and the ribs are the same as the hard holder 1.

Furthermore, the hard holder 30 is manufactured of resin having high transparency in the same manner as the hard holder 1. As resin having high transparency, the resin described above is preferable. Incidentally, when it is possible to confirm the state in the white blood cell remover, the resin is not required to be completely transparent, and the hard holder 1 may be manufactured of opaque resin.

[0059] Next, a method for forming the hard holder 300 will be explained. In the beginning, the first flat plate portion 32a including the first plate-like portion 321a and the second flat plate portion 32b including the second flat plate-like portion 321b are separately injection molded. Next, the side for housing the white blood cell remover 40 of the first flat plate portion 32a and the side for housing the white blood cell remover 40 of the second flat plate portion 32b are separately injection molded. Next, the side for housing the white blood cell remover 40 of the first flat plate portion 32a and the side for housing the white blood cell remover 40 of the second flat plate portion 32b are arranged so as to be located opposite to each other in an inward direction. The projection portion 33b manufactured on the second flat plate portion 32b in fit into the recessed portion 33a manufactured on the first flat plate portion 32b with the result that that the hard holder 30 is manufactured.

[0060] Next, a method for manufacturing the hard holder 30 according to another embodiment will be explained by using Fig. 4. In the beginning, the main body portion 32 is opened so that the white blood cell remover 40 is arranged on any one of the first flat plate portion 32a and the second flat plate portion 32b. At this time, the blood inlet port 46 is arranged on a portion constituting the upper end side penetration portion 35 while the

blood outlet port 47 is arranged on a portion constituting the lower end side penetration portion 36. Next, the first flat plate portion 32a and the second flat plate portion 32b are closed to fit the fixing projection portion 34b into the fixing recessed portion 34a thereby attaching the hard holder 30 on the white blood cell holder 40. In the case where the hard holder 30 is detached from the white blood cell remover 40, the procedure reverse to the procedure in the attachment method may be conducted. Through such process, the hard holder 30 can be easily attached on the white blood cell remover 40 before filtering while the hard holder can be easily detached from the white blood cell remover 40 after filtering.

[0061] Next, the hard holder for the white blood cells removal according to another embodiment will be explained. Fig. 5 is a perspective view showing the hard holder for the white blood cell remover according to another embodiment of the present invention. The hard holder 80 for the white blood cell remover according to this embodiment comprises the main body portion 82, and the main body portion 82 comprises the flat plate-like portions 821a and 821b located opposite to each other which contact both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover 40 at the time of usage and which are manufactured approximately in parallel to each other, and the interval between the flat plate-like portions 821a and 821b located opposite to each other of the main body portion 82 becomes the same as or larger than the thickness of the white blood cell remover 40. Furthermore, the main body portion 82 comprises the first plate portion 82a and the second flat plate portion 82b which can be attached on and detached from the first flat plate portion 82a and which becomes

parallel to the first flat plate portion 82a in an attachment state in which the white blood cell remover 40 is housed. Furthermore, the main body portion 82 comprises an upper end side penetration portion 85 which allows the blood inlet port 46 of the white blood cell remover 40 or the tube 416 connected to the blood inlet port 46 to pass therethrough, and a lower end side penetration portion 86 which allows the blood outlet port 47 or the tube 417 connected to the blood outlet port 47 to pass therethrough.

[0062] The hard holder 80 of the present invention comprises the main body portion 82, the upper end side penetration portion 85 and the lower end side penetration portion 86. As shown in Fig. 5, the main body portion 82 comprises the first flat plate portion 82a including the flat plate-like portion 821a and a second flat plate portion 82b including the second flat plate-like portion 821b. The first plate portion 82a and the second plate portion 82b are manufactured of different materials, and both portions are manufactured approximately in the same configuration. Furthermore, the main body portion 82 has fixing portions 84a and 84b on both end sides thereof so that the first flat plate portion 82a and the second flat plate portion 82b can be detached. The fixing portion 84a is manufactured as a recessed portion on both end sides of the flat plate portion 82. The fixing portion 84b is manufactured as a projection portion at a location corresponding to the fixing portion 84a of the second flat plate portion 82b. Then, the first flat plate portion 82a and the second flat plate portion 82b can be fixed to each other by fitting the fixing portion 84b which is a projection portion into the fixing portion 84a which is a recessed portion. Furthermore, with such a structure, after usage, the second flat plate portion 82b can be easily

detached from the first plate portion 82a. Incidentally, a method for fixing the second flat plate portion 82b to the first flat portion 82a is not limited to what has been described above. For example, the first flat plate and the second flat plate may be fixed by using different material.

[0063] Furthermore, in the state in which the state (closed state) in which the first flat plate portion 82a and the second flat plate 82b are closed to each other, the flat plate-like portion 821a and the flat plate-like portion 821b become parallel to each other. Inside of the main body portion 82, a space is manufactured for housing the white blood cell remover 40. In the embodiment, the inside size of the main body portion in the closed state is manufactured in a size which allows housing the white blood cell remover 40. In the same manner as the main body portion 2, the main body portion 82 comprises the flat plate-like portions 821a and 821b which contacts both surfaces of the soft resin-made bag-like housing 42 of the white blood cell remover 40 at the time of usage (closed state). An interval between the flat plate-like configurations 821a and 821b located opposite to each other of the main body portion 82 becomes the same as or larger than the thickness of the white blood cell remover 40. Furthermore, an interval between the flat plate-like configurations 821a and 821b located opposite to each other of the main body portion 82 becomes thinner than the thickness of the white blood cell remover in the case where the filtered substance is allowed to pass through the white blood cell remover without attaching the hard holder in the same manner as the main body portion 2.

[0064] Incidentally, the filtering rate of the white blood cell remover 40 may be adjusted by adjusting the interval between the flat plate-like portions

821a and 821b of the hard holder 80. Incidentally, when the inside of the main body portion cannot press the white blood cell remover 40 from the outside at the time of usage, and, at the same time, the interval of the flat plate-like portions located opposite to each other of the hard holder is the same as or larger than the thickness of the white blood cell remover and appropriately regulates the capacity of the blood chamber on the inlet port, the hard holder may be manufactured in any size and any configuration.

The size of the inside of the main body portion 82 of the hard holder 80 is preferably such that the interval between the flat plate-like portions 821a and 821b located opposite to each other increases by 0 to 3mm with respect to the thickness of the white blood cell remover, the length of the longitudinal direction which runs at right angle with the longitudinal direction of Fig. 5 increases by 0 to 3mm with respect to the white blood cell remover, and the length of the longitudinal direction of Fig. 5 increases by 0 to 3mm with respect to the width of the white blood cell remover.

Furthermore, in the state in which the white blood cell remover 40 is housed, the main body portion 82 comprises an upper end side penetration portion 85 which allows the blood inlet port 46 of the white blood cell remover 40 to pass therethrough on an upper end, and a lower end side penetration portion 86 which allows the blood outlet port 47 of the white blood cell remover 40 to therethrough on a lower end. Consequently, the hard holder 80 enables filtering with the white blood cell remover 40 even in the state in which the hard holder 80 is attached on the white blood cell remover 40.

[0065] The upper end side penetration portion 85 is manufactured as one circle with the overlapping of the semi-circle manufactured on the first plate

portion 82a and the semi-circle manufactured on the second flat plate portion 82b. Similarly, the lower end side penetration portion 86 is also manufactured. Incidentally, in the embodiment, the upper end side penetration portion 85 and the lower end side penetration portion 86 are manufactured in a circular configuration, but both penetration portions 85 and 86 may be manufactured in an oblong configuration. In the state in which the hard holder 80 is attached on the white blood cell remover 40, the blood inlet port 46 of the white blood cell remover 40 passes through the upper end side penetration portion 85 while the blood outlet port 47 of the white blood cell remover 40 passes through the lower end side penetration portion 86. As a consequence, the filtering can be conducted with the white blood cell remover 40 in the state in which the hard holder 80 is attached on the white blood cell remover 40. Incidentally, in the embodiment, the upper end penetration portion 85 is provided on a location corresponding to the blood inlet port 46 of the main body portion 82 while the lower end side penetration portion 86 is provided on a location corresponding to the blood outlet port 47 on a lower end side. However, the invention is not limited thereto. As long as the upper end side penetration portion 85 and the lower end side penetration portion do not hinder the flow of the liquid passing through the blood inlet port 46 or the tube connected to the blood inlet port 46 as well as the blood outlet port 47 and the tube 417 connected to the blood inlet port 47, both penetration portions may be manufactured at any locations on the upper end side (blood inlet port 46 side) of the main body portion 82 and on the lower end side of the main body portion 82 of the main body portion 82 (blood outlet port 47 side). Furthermore, the size of the

internal diameter of the upper end side penetration portion 85 and the lower end side penetration portion 86 is preferably set to -1mm or more and +10mm or less with respect to the external diameter of the port in the same manner as the hard holder 20. Incidentally, in the embodiment, in the state in which the hard holder 80 is attached on the white blood cell remover 40, the port 46 may pass through the upper end side penetration portion 85 while the port 47 may pass through the lower end side penetration portion 86. However, the invention is not limited thereto. The tube 416 may pass through the upper end side penetration portion 85 while the tube 417 may pass through the lower end side penetration portion 86. The internal diameter of the penetration portion in this case is preferably manufactured in a size of -1mm or more and +10mm or less with respect to the external diameter of the tube.

[0066] Furthermore, the thickness of the hard holder 80 is preferably set to 2mm or more at almost all the portions in the same manner as the case of the hard holder 1. As a formation material of the hard holder, the material same as the hard holder 1 is used. Incidentally, the thickness of the hard holder 80 is more preferably 2 to 3mm out of the scope of 2mm or more. Furthermore, the hard holder 1 comprises a plurality of projections (not shown) in the same manner as the hard holder 1. Furthermore, the hard holder 80 is preferably provided with a plurality of ribs (not shown) in the same manner as the hard holder 1. Incidentally, the sizes and the configurations of the projections and ribs is preferably the same as the hard holder 80. Furthermore, the hard holder 80 is preferably manufactured of resin having high transparency in the same manner as the hard holder 1.

As highly transparent resin, the resin same as the resin of the hard holder is preferable. Incidentally, when it is possible to confirm the state in the white blood cell remover, the hard holder may not be made of completely transparent resin. The hard holder may be manufactured of opaque resin.

[0067] Next, a method for forming the hard holder 80 will be explained. In the beginning, the first plate portion 82a including the first plate-like portion 821a and the second plate portion 82b including the second plate-like portion 821b are separately injection molded. Next, the side for housing the white blood cell remover 40 of the first flat plate portion 82a and the side for housing the white blood cell remover 40 of the second flat plate portion 82b are arranged so as to be located opposite to each other in an inward direction with the result that the projection portion 84b manufactured on the second plate portion 82b is fit into the recessed portion 84a manufactured on the first flat plate portion 82a. Thus, the hard holder 80 is manufactured.

[0068] Next, a method for using the hard holder 80 according to another embodiment will be explained by using Fig. 5. In the beginning, the main body portion 82 is opened to arrange the white blood cell remover 40 on the second flat plate portion 82b. At this time, the blood inlet port 46 is arranged on a portion constituting the upper end side penetration portion 85 of the second flat plate portion while the blood outlet port 47 is arranged on a portion constituting the lower end side penetration portion 86 of the second plate portion 82b. Next, the first flat plate 82a is closed into the second flat plate portion to fit the fixing portion 84a and the fixing portion 84b to attach the hard holder 80 on the white blood cell remover 80. In the case where the hard holder 80 is detached from the white blood cell remover 40, the

procedure is reversed from the procedure in the attachment method.

Through such procedure, the hard holder 80 can be easily attached on the white blood cell remover 40 before filtering while the hard holder can be easily detached from the white blood cell remover 40 after filtering. As described above, the hard holder for the white blood cell remover and the white blood cell remover have been explained. However, the constitution is not limited to what has been described above.

[0069]

[Effect of the Invention]

The hard holder for the white blood cell remover according to the present invention is a hard holder for the white blood cell remover which comprises a soft resin-made bag-like housing, a filtering member for the white blood cell remover provided for partitioning the housing into the blood chamber on the inlet side and the blood chamber on the outlet side, a blood inlet port communicating with the blood chamber on the inlet side, and a blood outlet port communicating with the blood chamber on the outlet side. The hard holder comprises a main body portion for housing the white blood cell remover, and the main body portion comprises flat plate-like portions which contact the white blood cell remover, and the interval between the flat plate-like portions located opposite to each other of the main body portion becomes the same as or larger than the white blood cell remover. As a consequence, the hard holder is attached on the white blood cell remover having soft resin-made housing to enable filtering of the white blood cell remover.

[0070] Furthermore, when the hard holder for the white blood cell remover

comprises the open portion for the insertion of the white blood cell remover provided on one end, a penetration portion provided on the other end to allow the port of the white blood cell remover or the tube connected to the port to pass therethrough, and a guiding notch portion for guiding the port which extends from the penetration portion to the open portion or the tube connected to the port, the hard holder can be easily attached on the white blood cell remover having the soft resin-made housing, and the hard holder can be easily detached easily after usage.

[Brief Description of the Drawings]

[Fig. 1] Fig. 1 is a perspective view showing a hard holder for a white blood cell remover according to an embodiment of the present invention.

[Fig. 2] Fig. 2 is a perspective view showing a hard holder for a white blood cell remover according to another embodiment of the present invention.

[Fig. 3] Fig. 3 is a perspective view showing a hard holder for a white blood cell remover according to another embodiment of the present invention.

[Fig. 4] Fig. 4 is a perspective view showing a hard holder for a white blood cell remover according to another embodiment of the present invention.

[Fig. 5] Fig. 5 is a perspective view showing a hard holder for a white blood cell remover according to another embodiment of the present invention.

[Fig. 6] Fig. 6 is a front view showing the white blood cell remover used in the hard holder for the white blood cell remover as seen from the side of the blood chamber on the inlet side.

[Fig. 7] Fig. 7 is a rear surface view showing the white blood cell remover of Fig. 6.

[Fig. 8] Fig. 8 is an enlarged sectional view taken long line A-A, the view

showing the white blood cell remover of Fig. 6.

[Fig. 9] Fig. 9 is a sectional view taken along line B-B, the view showing the white blood cell remover of Fig. 6.

[Fig. 10] Fig. 10 is a view showing a state in which the white blood cell remover shown in Fig. 6 is partially peeled off.

[Fig. 11] Fig. 11 is a view showing a filter member for the removal of white blood cells, the member being used in the white blood cell remover according to the present invention.

[Fig. 12] Fig. 12 is a sectional view showing a state in which the hard holder for the white blood cell remover is attached on the white blood cell remover.

[Fig. 13] Fig. 13 is a front view as seen from the side of the blood chamber on the outlet side of another white blood cell remover used in the white blood cell remover according to the present invention.

[Fig. 14] Fig. 14 is an enlarged sectional view taken along line C-C of the white blood cell remover of Fig. 13.

[Fig. 15] Fig. 15 is a perspective view showing another white blood cell remover used in the hard holder for the white blood cell remover according to the present invention.

[Fig. 16] Fig. 16 is a central sectional view of the white blood cell remover shown in Fig. 15.

[Reference Numerals]

1 hard holder

10 hard holder

20 hard holder

30 hard holder

40 white blood cell remover

42 soft resin-made housing

43 blood chamber on the inlet side

44 blood chamber on the outlet side

45 filter member for white blood cell remover

46 blood inlet port

47 blood outlet port

50 white blood cell remover

70 white blood cell remover

80 hard holder